PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Welcome and general update on PSCI

Manjit Singh

PSCI Chair

Associate Director of Corporate Sustainability, Centrient

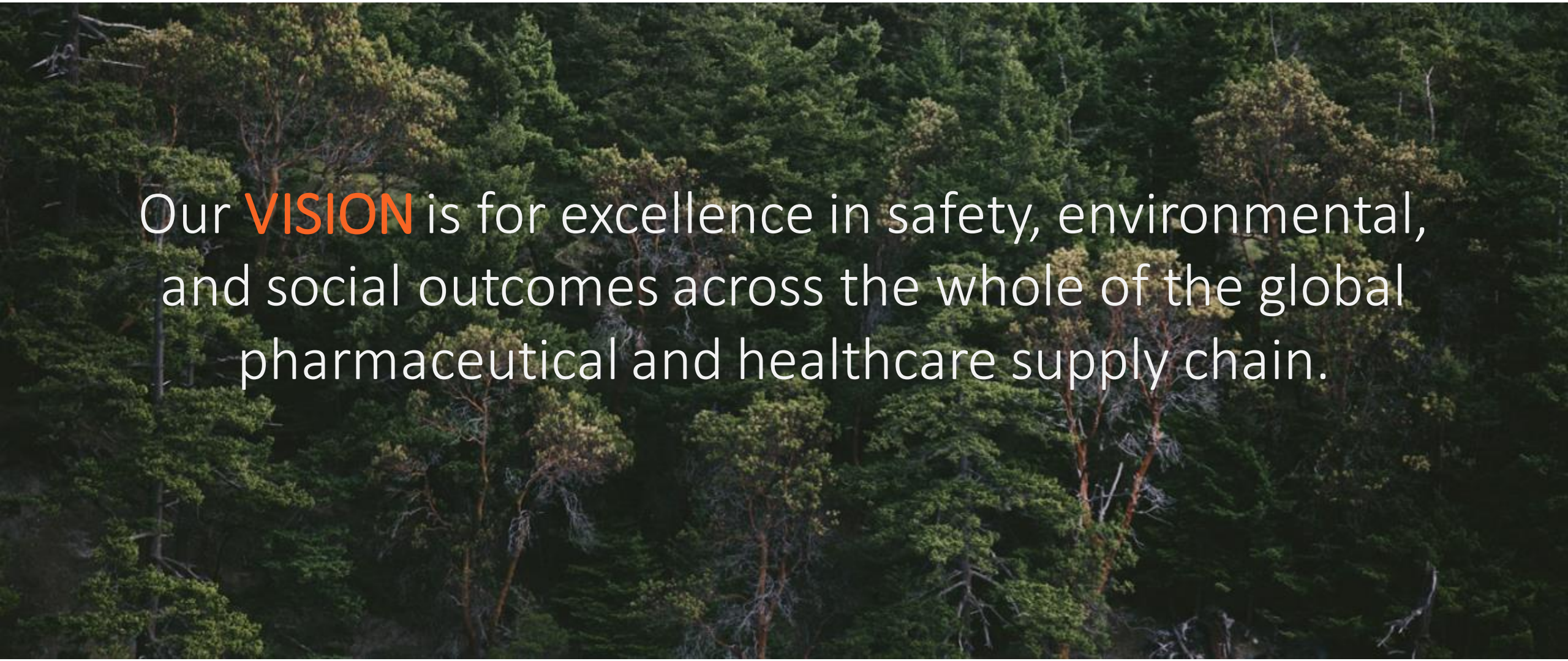
Agenda

The vision & introduction

What we do & 2021 highlights

Conference arrangement

PSCI: THE VISION



THE MEMBERSHIP

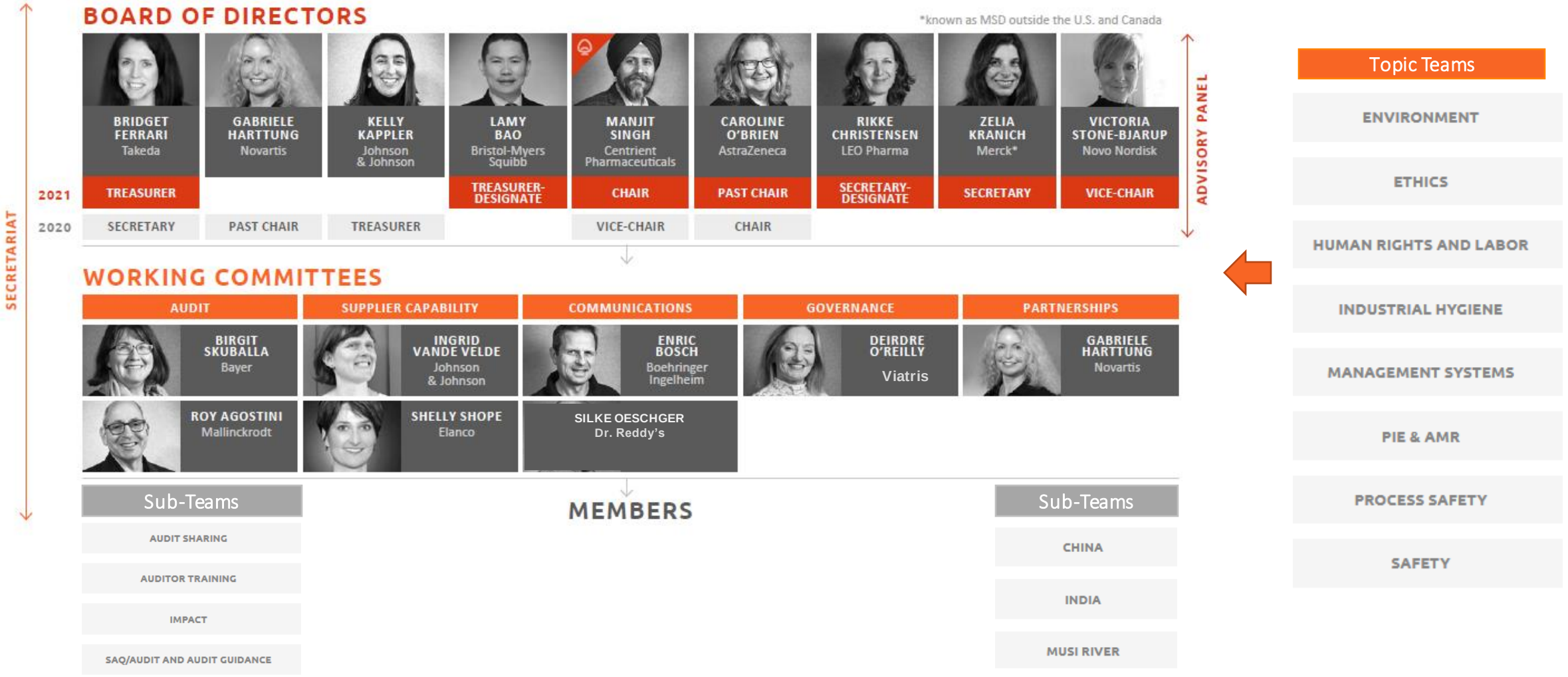
51 companies already share the PSCI VISION and are committed to continuous improvement in the supply chain

Members as of August 2021

**Associate members have the following symbol:*

The rest are full members.

HOW WE WORK



Topic Teams

- ENVIRONMENT
- ETHICS
- HUMAN RIGHTS AND LABOR
- INDUSTRIAL HYGIENE
- MANAGEMENT SYSTEMS
- PIE & AMR
- PROCESS SAFETY
- SAFETY

HOW WE WORK

TOPIC TEAMS

ENVIRONMENT

RIKKE CHRISTENSEN
LEO Pharma

ZELIA KRANICH
Merck & Co.

ETHICS

MANJIT SINGH
Centrient Pharmaceuticals

ANN-CHRISTINE EIESLAND
AstraZeneca

HUMAN RIGHTS AND LABOR

LAURENT LHOPITALLIER

PETER NESTOR
Novartis

INDUSTRIAL HYGIENE

VIVIAN RIVERA TURRO
Lilly

BEVERLY HILES
Elanco Animal Health

MANAGEMENT SYSTEMS

BRIDGET FERRARI
Takeda

PIE & AMR

PAUL BARNETT
GSK

SAM MAYNARD
AstraZeneca

PROCESS SAFETY

DANIEL REHM
Elanco Animal Health

VIJAYA KUMAR BENDI
Johnson & Johnson

SAFETY

LAMY BAO
Bristol-Myers Squibb

**Sub-Team leads as at August 20-21*

HOW WE WORK

PARTNERSHIPS COMMITTEE

Dedicated to pursuing partnerships with other industry organisations.

CHAIR

GABRIELE HARTTUNG
Novartis

CO - CHIAR

SIMON HODGSON
Secretariat

China Sub-Team

BARRY BAI
Elanco Animal Health

KELLEY JIANG
Novartis

CHINA GROUP

India Sub-Team

BHARAT SHEVKAR
Johnson & Johnson

MANJIT SINGH
Centrient Pharmaceuticals

INDIA GROUP

Our partnerships in China and India

RDPAC

Research & Development based Pharmaceutical Association China

- Agreement letter sent
- Regular contacts and meetings
- Mutual conference exchanges

CPEA

China Pharmaceutical Enterprise Association

- MoU in place
- Regular contacts and meetings
- Mutual conference exchanges
- Start using our SAQs

KDPMA

Karnataka Drugs & Pharma Manufacturers Association

- MoU in place
- Have established a healthy relationship
- Exchange of PSCI promotional, other material and invite to key events.

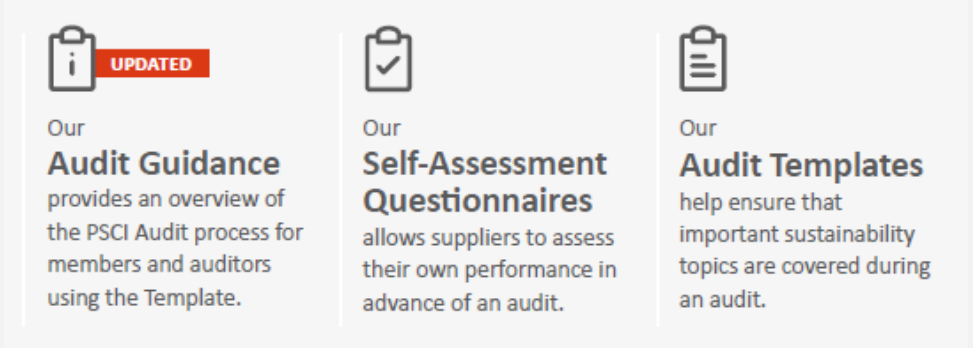
→ We are also currently exploring further partnering opportunities in India. We are in contact with IDMA and IGCW.

WHAT WE DO

AUDIT AND AUDIT SHRAING

- *A common voice* for the industry. Our practical *Supplier Assessment Tools represent* shared expectations around *Management*, *Ethics*, *Labor*, *Health and Safety*, and *Environment* topics.

- *Reduce burden on the industry* by promote *Audit Sharing* among member companies. By 2021 Q2, there are *548 audits* on our platform, *375* of them shared with PSCI members. We also Support *Supplier Self-initiated Audits* for suppliers to take initiative in risk assessment and share the responsibility in building sustainable businesses.



- Provide unique insights into the pharmaceutical and healthcare supply chain. Our *annual Analysis of Audit Findings* identifies areas for improvement and development trends to inform Supplier Capability building and drive continuous improvement in the supply chain.

- *Adapt and Innovate.* We developed *Remote Audit Guidance* in response to Covid 19. A *Moving SAQ Online project* was launched in 2020 to digitalise the process of Supplier audit.

- *Auditor training for approved 3rd party audit firms* to improve *audit quality* and ensure consistent application of PSCI standards. We hold annual Audit Partner events and review meetings to hear their *first hand experience with suppliers* and PSCI audits and protocols.

↑ **15**

REMOTE AUDITS SHARED IN 2020

WHAT WE DO

SUPPLIER ENGAGEMENT AND CAPABLITY BUILDING

- We organize **webinars** every year on a range of topics. **14 webinars were held** in 2020, reaching over **850 viewers**.

Top 5 webinars for 2020

1	2	3	4	5
Updates to PSCI Audit Guidance	PiE/AMR	Industrial Hygiene	Using the Ecodesk platform	Process Safety

"I'm delighted to see that the PSCI is maintaining its focus on audit sharing and supplier capability building – both critical elements of the PSCI program. Extensive supplier training and interaction, coaching, and mutual sharing of best practices is – in my view – the single biggest opportunity for the organization to improve environmental health, safety, and social standards in the supply chain and I'm excited to see what the PSCI does next in this area."

NGRID VANDE VELDE
Senior Manager EHS&S External Supply EMEA - ASPAC, Johnson & Johnson

- **Building a supplier community.** Interactive platform for members, suppliers and partners to

gain greater visibility and control over shared audits

hear about PSCI developments and updates

access PSCI tools, trainings and resources

- Every year, we hold **Supplier Conferences** in key sourcing regions. The 2020 Virtual Supplier Conferences contained **51 virtual training sessions**, reaching over **700 suppliers** from China and India.

WHAT WE DO

A COMMUNITY FOR KNOWLEDGE AND RESOURCES SHARING

JOIN THE COMMUNITY - THE LINK

Our online platform for members and suppliers

View shared **supplier audits**

Access **tools, training** and **other resources**

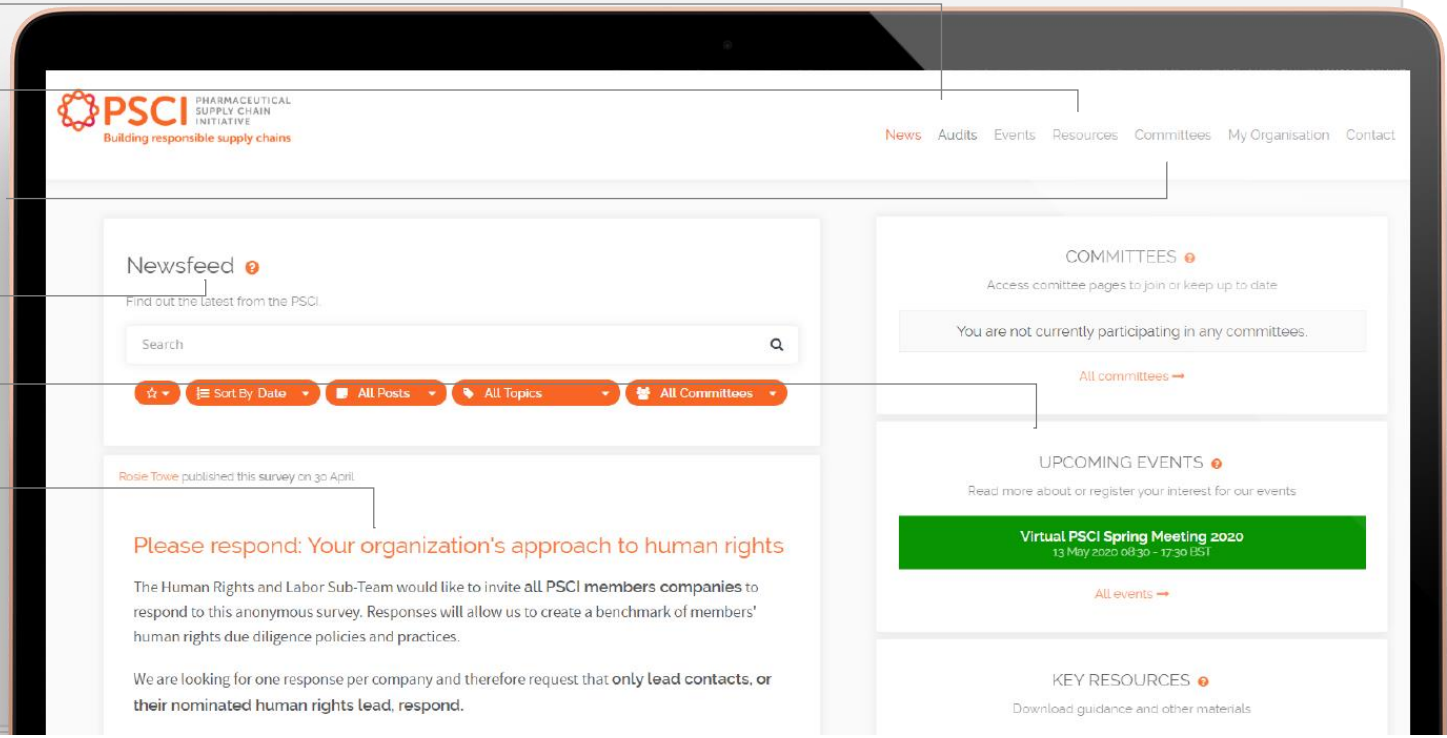
Check out the work of our **Committees and Sub-Teams**

Hear and comment on the latest **industry news**

Register for **events** and activities

Engage with peers through **polls, surveys** and sharing **ideas**

Sign up for the **peer to peer mentoring programme**



2021 highlights

Capability Committee

- **Webinars:** Delivered 7 webinars since January 2021
- **Future Planning:** Laid the groundwork for enhanced & structured supplier training
  - **8 maturity models** developed/drafted
  - **Master curriculum** built from individual content plans
  - **23 primers** launched so far (more in the pipeline)

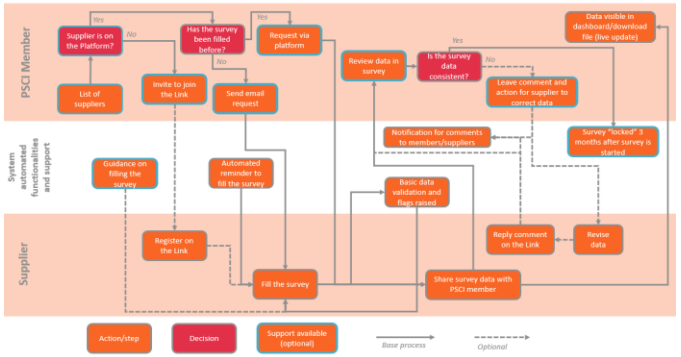
Governance Committee

- Kick-starting PSCI's supplier impact team

PSCI Environmental Survey for suppliers on the Link

- Environmental Survey **developed by the PSCI Environment team**
- The survey was hosted on the Ecodesk platform, but not used widely by PSCI members
- Built into the Link to be **free of access for members and suppliers**
  - The objective is to promote the use of the unified set of questions from the PSCI Environmental questionnaire, to alleviate supplier data collection (same data points)
- Suppliers can control who they share their data with
- Launched **April 2021** (with an introductory webinar)
- **Guidance** available online detailing process and functionality

Objectives:
- Allowing members to run the PSCI environmental questionnaire on a free platform
- Giving members more control over the survey and data collected
- Reduce burden on suppliers by allowing the sharing of responses



Establish programme

4 questions on environmental sustainability programmes and the PSCI code of conduct/principles.

Manage Impacts

Questions on Energy, GHG, Waste and Water.

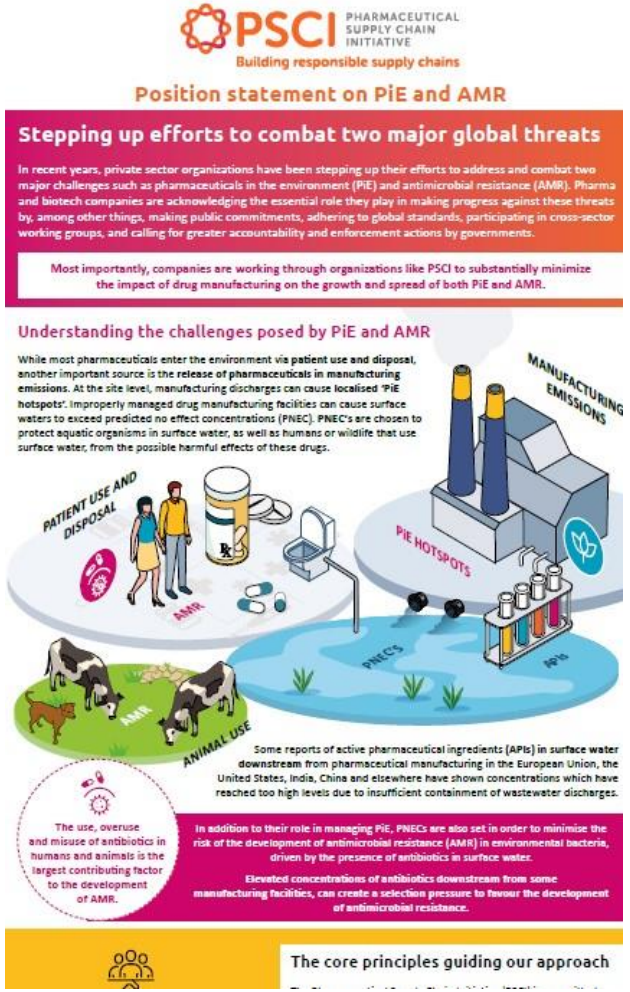
Reduce Emissions

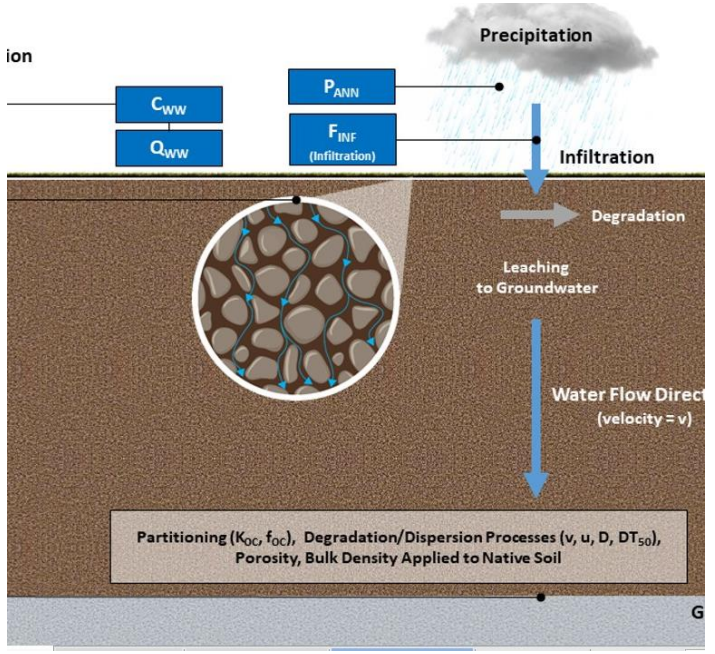
Questions on GHG emissions reduction targets (SBTi included) and progress to meet them. Also covers energy, water and waste reduction targets/programmes.

Apportion emissions

PIE/AMR

- In 2021 the PiE AMR team have developed the following and are now available on the Link:
  - Position statement developed on the importance of PiE and AMR
  - PiE and AMR Supplier Training Primer
- Current work in progress
  - Developing models that can be used to estimate API losses during manufacturing and API wastewater releases to soil and sludge
  - Developing a position paper on the low contribution of global emissions from manufacturing and the importance of local assessments





Other PiE & AMR Resources Available

- PEC/PNEC Calculator tool for assessing API losses
- A series of webinars :
  - Managing APIs in manufacturing effluent Part 1 - 27th Jan 2016: Introduction to the topic, the maturity ladder concept, how to calculate discharge concentrations, and steps to take to reduce API losses
  - Managing APIs in manufacturing effluent Part 2 - 15th June 2016 Case studies on how to put theory into practice; estimating API losses from the manufacturing process, establishing the acceptable discharge concentration (PNEC), and making low capital investment housekeeping steps to reduce API environmental emissions
  - Managing APIs in manufacturing effluent Part 3 - 25th October 2016: More advanced steps and technologies to reduce API levels in wastewater effluent
  - Managing APIs in manufacturing effluent Part 4 - 10th July 2018: A refresher on PiE, AMR and PNEC first principles, and introduce a PSCI resource page where PNECs can be found
  - Antimicrobial Resistance 23 July 2019: Introduction to AMR and how to calculate predicted environmental concentrations (PECs) of APIs in rivers, lakes and the sea. Where to find publicly available PNEC values for APIs:
  - Wastewater treatment technologies – 10th Sept 2020: Best practice wastewater treatment methods for managing the release of APIs into the environment from pharmaceutical manufacturing sites.
- Further training material is also available on PiE and AMR from the Indian and Chinese PSCI Supplier conferences held in 2018-2020:
  - A technical deep dive seminar exploring and providing training on the key issues and how sites can manage the release of APIs into the environment took place at a Supplier Conference in Hyderabad, India in September 2019.
  - China Supplier Conference September 2018: In slides 127-208 there is an introduction to environmental risk assessment, AMR, PNECS and setting site discharge limits and case studies in controlling API in wastewater effluent (in Chinese)
  - Supplier conferences 2020: Focussed session on PiE & AMR available here in English and here in Chinese . Topics covered include: sampling & analysis, mass balance calculation, WWT technology plus case studies. The resources are tagged beneath the event description.

2021 highlights

Communication Committee

- Published PSCI Annual Report 2020
- Launched PSCI Principles video

Partnership Committee

- Potentially set up local team for other markets
- Musi River Project (next slide)

Musi River Project

- Context:
  - Beautiful river in Hyderabad
  - NGO reports about its pollution with potential connection to the pharma sector
  - PSCI had fruitful discussion with report authors Nordea
  - First Musi river project: Reached out to suppliers to offer our resources & statement of public support of State of Telangana's revitalisation initiative
- Relaunch of the Musi river project
  - Database of 100+ pharmaceutical suppliers in Hyderabad, around 40 with direct link to PSCI
  - Baseline analysis of their wastewater technologies in place

Upcoming webinars

Team Lead	Topic	Date
Capability HR&L	PSCI Capability vision and status of content development Latest developments of human rights law	4 February 25 February
Environment	The PSCI Environmental survey on the Link (member version and supplier version): a demo of the new survey we are building on the platform	12 April 15 April
Safety	New Maturity Model for Safety & Arc Flash Hazard and Prevention	6 May
Industrial Hygiene	Containment & Exposure Assessment	27 May
PSM	Explosion protection (part 1)	8 July
India	Indian labour law changes	22 July
PSM	Explosion protection (part 2)	12 August
PiE/AMR	Risk Assessment Tools – Discharge Of APIs In Sludge & Wastewater	15 September
Environment	Scope 3 emissions	30 September
PiE/AMR	Arcadis webinar	14 October
Ethics	Pharma industry practices and PSCI perspective on the animal use in testing and experimentation	28 October
PSM	Storage of hazardous chemicals *(topic may change)*	11 November
India	*Topic TBC*	November

Conference arrangement

- Three half-day event, covering management systems, environment, health & safety and labor topics
- Best practice and regulation updates from industry experts
- 20 min ***networking break*** with other attendees at the end of each day
- ***Feedback survey*** will be distributed at end of each day as well to collect detailed comments around content and event organization

You'll hear speakers from…

3M
Dr. Reddy's
HETERO
CENTRIENT Pharmaceuticals
ERM
Alembic
Mylan
Johnson & Johnson
NOVARTIS

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

Wastewater Treatment
Zero Liquid Discharge, Effective Pre-treatment

Prasanna. Hota

Associate Vice President-EHS

Viatris.

ANTI-TRUST STATEMENT

"While some activities among competitors are both legal and beneficial to the industry, group activities of competitors are inherently suspect under the antitrust/anti-competition laws of the US, UK and other countries in which our companies do business. Agreements between or among competitors need not be formal to raise questions under antitrust laws, but may include any kind of understanding, formal or informal, secretive or public, under which each of the participants can reasonably expect that another will follow a particular course of action or conduct. Each of the participants in this meeting is responsible for seeing that topics which may give an appearance of an agreement that would violate the antitrust laws are not discussed. It is the responsibility of each participant in the first instance to avoid raising improper subjects for discussion, such as those identified below.

It is the sole purpose of this meeting to provide a forum for expression of various points of view on topics described in the agenda and participants should adhere to that agenda. Under no circumstances shall this meeting be used as a means for competing companies to reach any understanding, expressed or implied, which tends to restrict competition, or in any way to impair the ability of members to exercise independent business judgment regarding matters affecting competition.

Topics of discussion that should be specifically avoided are:

i. price fixing;
ii. product discounts, rebates, pricing policies, levels of production or sales and marketing terms customer and territorial allocation;
iii. standards setting (when its purpose is to limit the availability and selection of products, limit competition, restrict entry into an industry, inhibit innovation or inhibit the ability of competitors to compete);
iv. codes of ethics administered in a way that could inhibit or restrict competition;
v. group boycotts;
vi. validity of patents;
vii. on-going litigation;
viii. specific R&D, sales or marketing activities or plans, or confidential product, product development, production or testing strategies or other proprietary knowledge or information."

AGENDA

- About Viatris
- What is ZLD & Why is it important
- Wastewater Composition & Recommended Treatment
- ZLD Treatment Flow
- Pre-Treatment – Primary, Secondary & Tertiary
- Case Studies

SPEAKER BIO

- Name: Prasanna. Hota
- Job Title: Associate Vice President - EHS
- Organization: Viatris.
- Organization Profile (optional)
- Contact : 0091 8008001622, prasanna.hota@viatris.com

- A post graduate in Environmental Engineering , with over 25 years hands on experience in wastewater treatment & recycling in various industrial sectors like Pharmaceutical, Textiles, Distilleries , Common Effluent Treatment Plants etc.

About Viatris

- Viatris was formed in November 2020 with the combination of Mylan and Upjohn, a legacy division of Pfizer.
- Viatris - empowers people worldwide to live healthier at every stage of life.
- At Viatris, we believe in healthcare not as it is, but as it should be.
- We provide access to medicines, advance sustainable operations, develop innovative solutions and leverage our collective expertise to improve patient health.

Highlights:

- More than 40,000 work force across 70+ countries.
- More than 80 Billion doses sold across 165 countries.
- Focused EHS policies, Robust EHS Management systems to ensure minimum impact to Environment.
- Several sites certified for Environmental Management System like ISO 14001 , Health & Safety Management system like OHSAS 18001 and are now migrating to ISO 45001 and Energy Management system like ISO 50001.
- Our CDP scores on Water security is “B” and Climate change “B -”
- Legacy Mylan is signatory of Davos Declaration on combating AMR and founding Board member of AMR Industry Alliance.

Zero Liquid Discharge (ZLD)

What is Zero Liquid Discharge (ZLD)??

- As the name suggests there is no discharge of wastewater when implemented properly.
- Entire wastewater is treated through various treatments and is reused.
- Recycled water from ZLD is used in Non-potable applications like Utilities.

Why ZLD ??

- High efficiency treatment.
- Avoids discharge of industrial pollutants through treated wastewater.
- Helps in conserving precious natural resource i.e., Fresh water.
- Efficient treatment option for AMR control, PiE through wastewater.

Wastewater Composition Vs Treatment

Characteristic	Treatment
Acidic/ alkaline (pH)	Neutralization
Colour	Primary Treatment (Coagulation, Floculation, Sedimentation)
Oil & Grease	Primary Treatment (Floatation, Dissolved air floatation)
Metals	Primary Treatment with alkaline precipitation
Solvents	Stripping
Odour	Carbon adsorption
Organics.	Biological treatment for Biodegradables
Solids Soluble (TDS) / Insoluble (Suspended & settleable)	Primary for Insolubles and Desalination with RO, Evaporator for solubles
Nutrients like N, P etc.	Nitrification, Denitrification for Nitrogen, Biological precipitation for Phosphorus

ZLD Flow diagram for a typical Pharmaceutical manufacturing unit.

High TDS/COD

Primary treatment

Stripper, MEE, ATFD

Low TDS/COD

Primary treatment

Biological treatment

Ultrafiltration

Multi -Stage Disc RO plant

Sludge dewatering

Recycled water to Utilities like CT , Boilers

RO rejects back to MEE& ATFD

Efficient Pre-Treatment Technologies to Improve RO Performance

- Majority of the Desalination happens through Reverse osmosis.
- For sustainable RO operation (long membrane life) effective pre-treatment of wastewater is very important.
- The pre-treatment shall be able to remove/ reduce membrane foulants like Organics, particulates, microbes and inorganics like Hardness, silica etc.
- Some of the efficient pre-treatment options are
  1. Primary treatment to remove suspended solids, colour, Oil & Grease.
  2. Biological treatment – ASP/SBR/ MBR
  3. Advanced filtration systems like Disk & Glass media filtration, MBR/ Ultrafiltration.
  4. Disinfection.
  5. Desilication/ Hardness removal for higher recovery through RO plants.
  6. Other Important aspects like
     - Temperature Effect
     - SDI.
     - Eudragit – Coating solution separation

Primary Treatment

Purpose : To remove Suspended solids, Oil & Grease, Colour from wastewater.

Achieved through - Coagulation, Flocculation, Sedimentation/ Floatation -

Relevance

- Suspended solids
  - avoid choking of Stripper Media.
  - choking of heat transfer tubes in calendrias.
  - Ensure healthy MLSS,MLVSS ratio in Biological treatment.
- Oil & Grease
  - Interferes in Oxygen transfer
  - food diffusion.
  - Membrane fouling if it carried forward to RO.
- Color
  - Aesthetics
  - Fouling in membranes based on composition.

Biological Treatment through ASP/ SBRs

- Activated Sludge process with its process modifications like extended aeration are proven over years for removal of biodegradable organics.

- Recent developments like Sequential Batch Reactor Technology (SBR) – is more effective due to …

  - Cyclic operation viz: Fill, Aeration, sedimentation & Decantation.
  - Complete quiescent conditions while sedimentation unlike conventional clarifiers where there is continuous feed & overflow during operation.
  - Higher Surface area than a clarifier.
  - Better Nitrification & Denitrification can be achieved.
  - Better Biological Phosphorus removal.

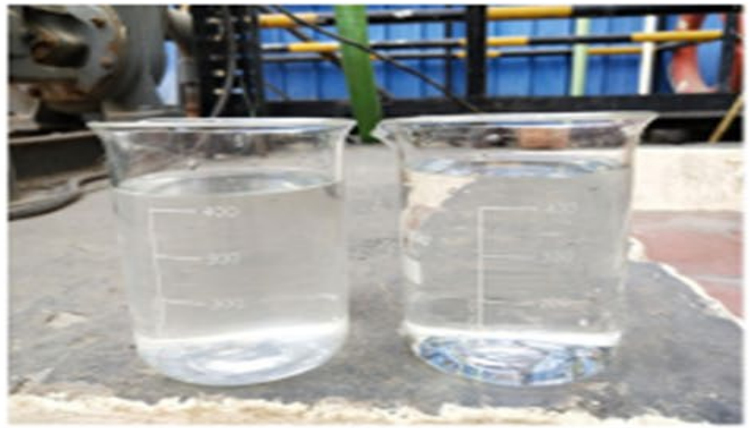
Filtration - Disk & Glass Media Filtration

- Traditionally Sand Filters, Carbon filters are used as pre-treatment filtration to RO systems.
- Advanced technologies like Disk & Glass media filters are gaining popularity due to their higher filtration efficiency, effective back wash with lesser water.

Auto clean disc & Glass media filtration

Glass and Activated carbon filter media

Auto clean filter system



Turbidity of Feed water – 15 NTU
Turbidity of Filtered Water - <1 NTU

Consumption of Cartridge filters, bag filters have come down in RO pre-treatment with Disk & Glass media filter usage

UF/ MBR as RO Pre-Treatment

- UF/MBR is a good pre-treatment step that helps in removing turbidity & particulates, thereby prevents fouling of membranes due to particulates & colloids
- Due to feed turbidity restrictions about 200 NTU, plants with higher turbidity, MBR modules is better option as these membranes are designed for higher turbidity/suspended solids.

Disinfection

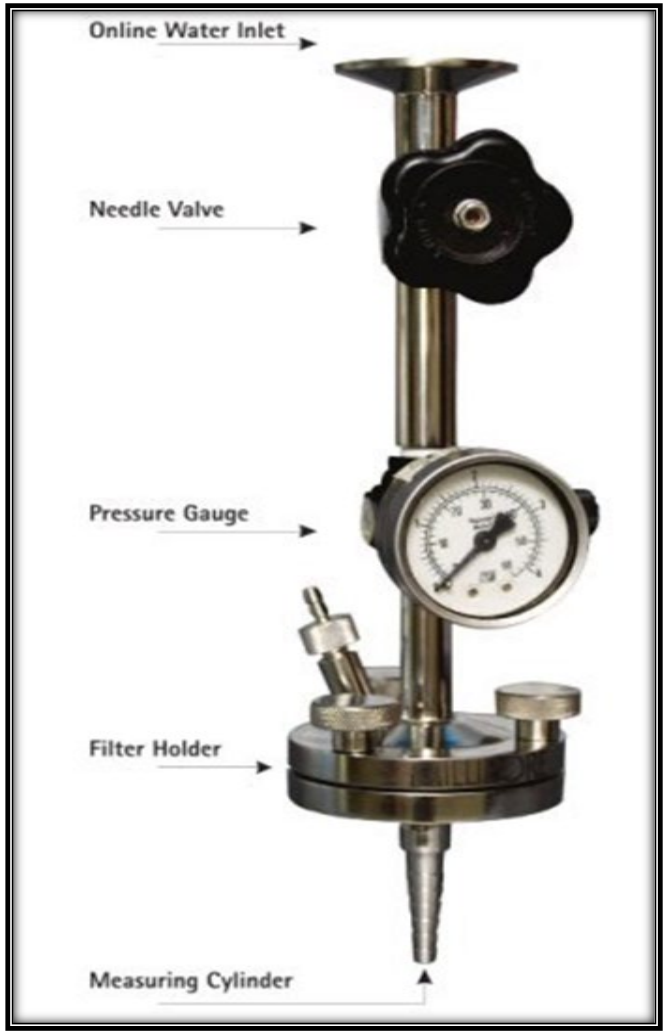
- Disinfection is an important pretreatment to RO systems especially for RO systems preceded with Biological treatment.
- Filtration systems like Sand , carbon filters and even RO membranes have good surface area for bacteria to grow and feed containing organics makes these systems vulnerable to Biofouling.
- Periodical pretreatment disinfection helps in avoiding Biofouling of membranes. Online nonoxidizing biocides are available to avoid Biofouling.
- Disinfection with Oxidizing biocides like Chlorine, Hypo solution are the conventional choices. However, Oxidizing biocides damage Polyamide RO membranes through Hydrolysis
- Nonoxidizing biocides are preferred. It's a good practice to periodically change nonoxidizing biocides to avoid bacteria to get acclimatize to these biocides.

Silica – Desilication

- At pH below 9, silica is present in the form of silicic acid. At low pH it can polymerize to form colloidal silica.
- At high pH, it can precipitate along with Calcium, magnesium and once it precipitates, it is very difficult to redissolve.
- Desilication through Lime, dolomite, soda ash is effective in precipitating the silica in pretreatment. Dosage of these chemicals depend on water chemistry.
- Silica specific antiscalants are also effective to some extent depending upon silica concentration.
- Ammonium Bi fluoride is used for cleaning of membranes fouled with Silica, but its handling is Hazardous.

Silt Density Index (SDI) – Fouling Index

- Indicates fouling potential on the membrane.
- SDI < 3 low, 3-5 is normal, > 5 High fouling potential.
- Tested through a filter paper of 0.45 Micron pore size, 47 mm dia @ 30 psi pressure, ideally for 15 minutes.
- t_0 - Initial time for filtering 500 ml water through SDI kit.
- t_T - Time to filter 500 ml after time T (5,10 or max 15 min)
- SDI : 100 x (1- t_0 / t_T)/T



Membrane Selection

- Depends on quality of feed water.
- Quality of permeate required.

- Important aspects while selecting membranes..
  - Salt rejection.
  - Feed channel spacer for spiral wound membranes.
  - Membrane area.
  - Cross flow requirements.
  - Low fouling membranes.

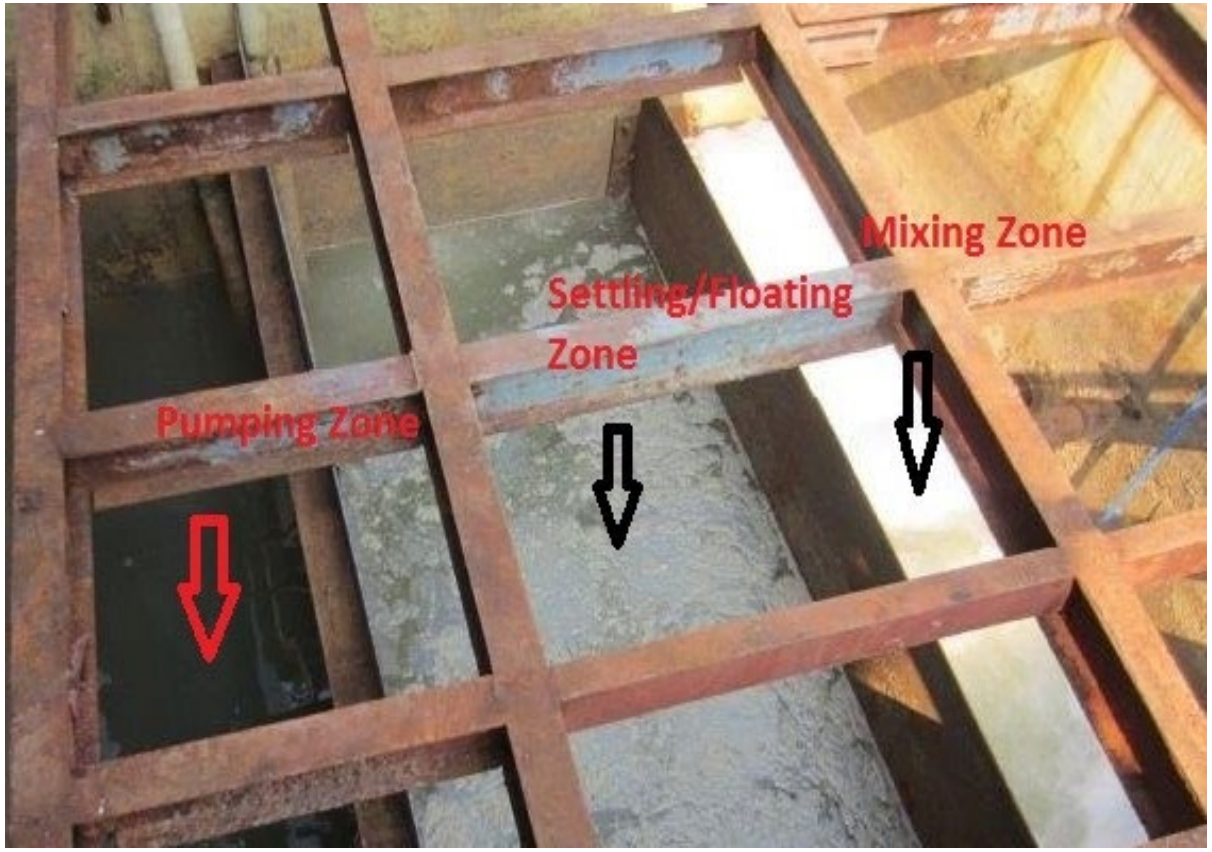
Effect of Temperature & Aluminium on RO

- Temperature
  - Temperature of wastewater plays a very important role in RO design.
  - For every degree increase in temperature, there will be 3% increase in permeate quantity but 5% increase in salt passage.
  - While designing RO plants for colder climates, temperature correction factor shall be considered.

- Aluminum
  - In pretreatment if aluminum is used as coagulant, it may affect RO membrane as this molecule is highly charged.
  - Aluminum is less soluble in water between pH 5.3 to 8.0 and may precipitate out of water and due to high charge will foul the membrane.

Case Study 1: Eudragit in Wastewater.

If coating solution contains Eudragit, its traces agglomerate and forms scum resulting choking of Filters, Ultrafiltration & RO plants.



Its separation required

- Mixing in first chamber
- Quiescent condition in second chamber where Eudragit float.
- Taking the water from third chamber with bottom entry.

Sustainable Solutions to AMR.

- Viatris is committed to working with stakeholders across the industry to combat antimicrobial resistance (AMR), which occurs when bacteria evolve to withstand the effects of antibiotics.
- Many factors contribute to AMR, including poor infection control, over-prescribing of antibiotics, and antibiotics in the environment.
- Most antibiotics in the environment are the result of human and animal excretions while a significantly smaller amount is from the manufacturing of active pharmaceutical ingredients and their formulation into drugs.

On AMR mitigation :

- We are a signatory to the Davos Declaration on combating AMR and a founding board member of the AMR Industry Alliance.
- We have adopted the AMR Industry Alliance Common Antibiotic Manufacturing Framework and are an active member of its manufacturing working group.
- Applied the Common Antibiotic Manufacturing Framework across all sites.
- We conduct risk assessments using the discharge target values published by the AMR Industry Alliance to assess potential risk of release of antibiotics from production, and if needed, take corrective action.
- We also have communicated with all AB suppliers the expectation to adopt the framework.

Case Study 2: ZLD for AMR / PiE control

- Since there is no discharge of wastewater, potential contribution to antibiotics and risk of resistant bacteria in the environment from wastewater discharge is avoided.
- Membrane efficiency on salt rejection is tested on Sodium chloride solution.
- Chloride being monovalent its rejection is lowest in an RO membrane. Even this lowest value is more than 99% for Polyamide membranes.
- As the ability of RO membrane (polyamide) to reject bigger molecules is high (> 99%), the recovered water is free from AB.
- This has been demonstrated in our trials on several antibiotic molecules like Clarithromycin , Enrofloxacin etc.
- Solid waste generated from ZLD operations is disposed under controlled conditions to authorized disposal facilities.

QUIZ / POLL

- Please feel free to add quiz or live polling if you would like to interact with the audience.

CONTACT

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PSCI

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About the Secretariat
Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

carnstone
partners ltd

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

A watershed moment: Novartis initiative towards water neutrality

Sudhir Bhagwat

Head HSE Supplier Assurance & Risk and Watershed, India region

23rd Sept. 2021

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iv. codes of ethics administered in a way that could inhibit or restrict competition;
v. group boycotts;
vi. validity of patents;
vii. on-going litigation;
viii. specific R&D, sales or marketing activities or plans, or confidential product, product development, production or testing strategies or other proprietary knowledge or information."

AGENDA

- Novartis – Environment Sustainability
- Need for Water Conservation
- Community Watershed Project
- Achievements
- Photos

SPEAKER BIO

Heading HSE Supplier Assurance & Risk and
Watershed function for India region

Tasks:
Managing Novartis HSE TPRM Program for India region.
Implementation of Watershed program

Educational Background:
Chemical Engineering & Adv. Dip. In Industrial Safety

Experience:
Around two decades in the field of HSE and Manufacturing

Sudhir Bhagwat
Head HSE Supplier Assurance
& Risk and Watershed, India
sudhir.bhagwat@novartis.com

Vas Narasimhan

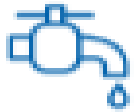
Chief Executive Officer

Novartis Environmental Sustainability: A race we can win

- Environmental sustainability: a race we can win - YouTube

Novartis Environmental Sustainability Goals

Environmental Sustainability targets, 2025 and 2030

	Our ambition	Targets 2025	Targets 2030
Climate 	**Carbon neutrality**	1 Carbon neutral own operations Scope 1 and 2	3 Total carbon footprint neutrality scope 1, 2 & 3
		2 Environmental criteria in all supplier contracts	
Waste 	**Circular economy & plastic neutrality**	4 Eliminate PVC in packaging	6 Plastic neutral
		5 Waste disposal reduced by half	7 All new products meet sustainable design principles
Water 	**Water sustainability**	8 Water consumption reduced by half in our operations	10 Water neutral in all areas
		9 No water quality impacts from manufacturing effluents	11 Enhance water quality wherever we operate

Strategic priorities of Novartis

- Unleash the power of our people
- Deliver transformative innovation
- Embrace operational excellence every day
- Go big on data and digital
- Build trust with society

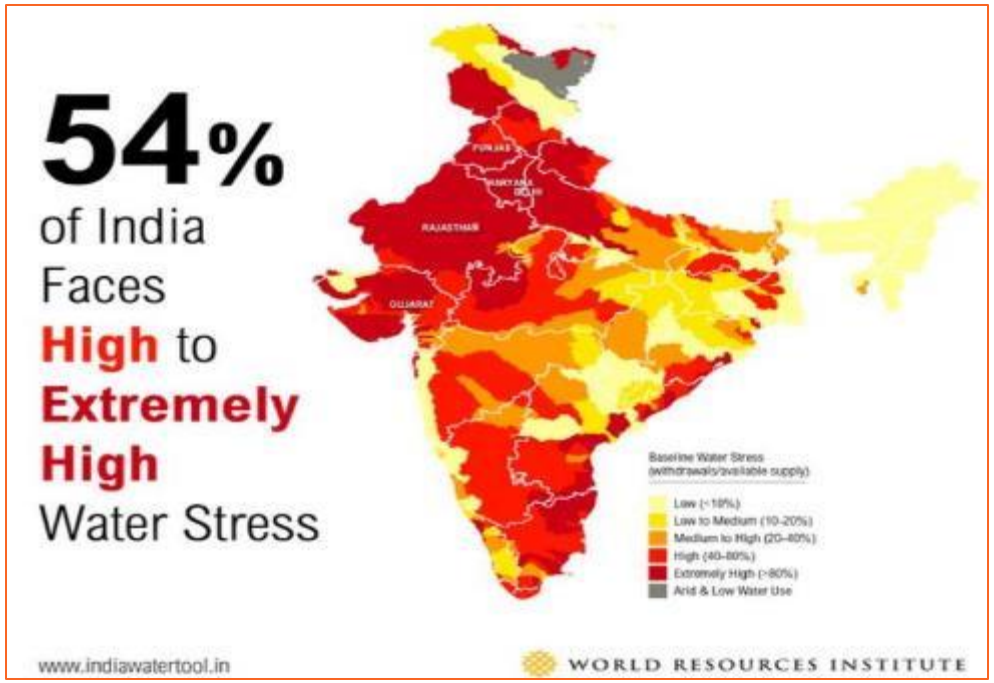
Build trust with society

Novartis aspires to be the most valued and trusted medicines company in the world. We work to build trust with customers, patients, partners, associates and society more broadly. We do this by making our medicines accessible to as many people as possible and addressing priority global health issues, while embedding ethics into our business and becoming a more sustainable and responsible company.

- Through our Healthy Family programs in India, we educate rural communities on water, sanitation and hygiene (WASH) antimicrobial resistance and safe disposal of medicines.
- Our first attempt in supporting Healthy family program by ensuring water availability and sanitation facilities Novartis Launched Community watershed Project on world water day 22nd March 2021.

Water – Our Necessity

Can you imagine that when you wake up there is no water to drink?



India – Water Challenges

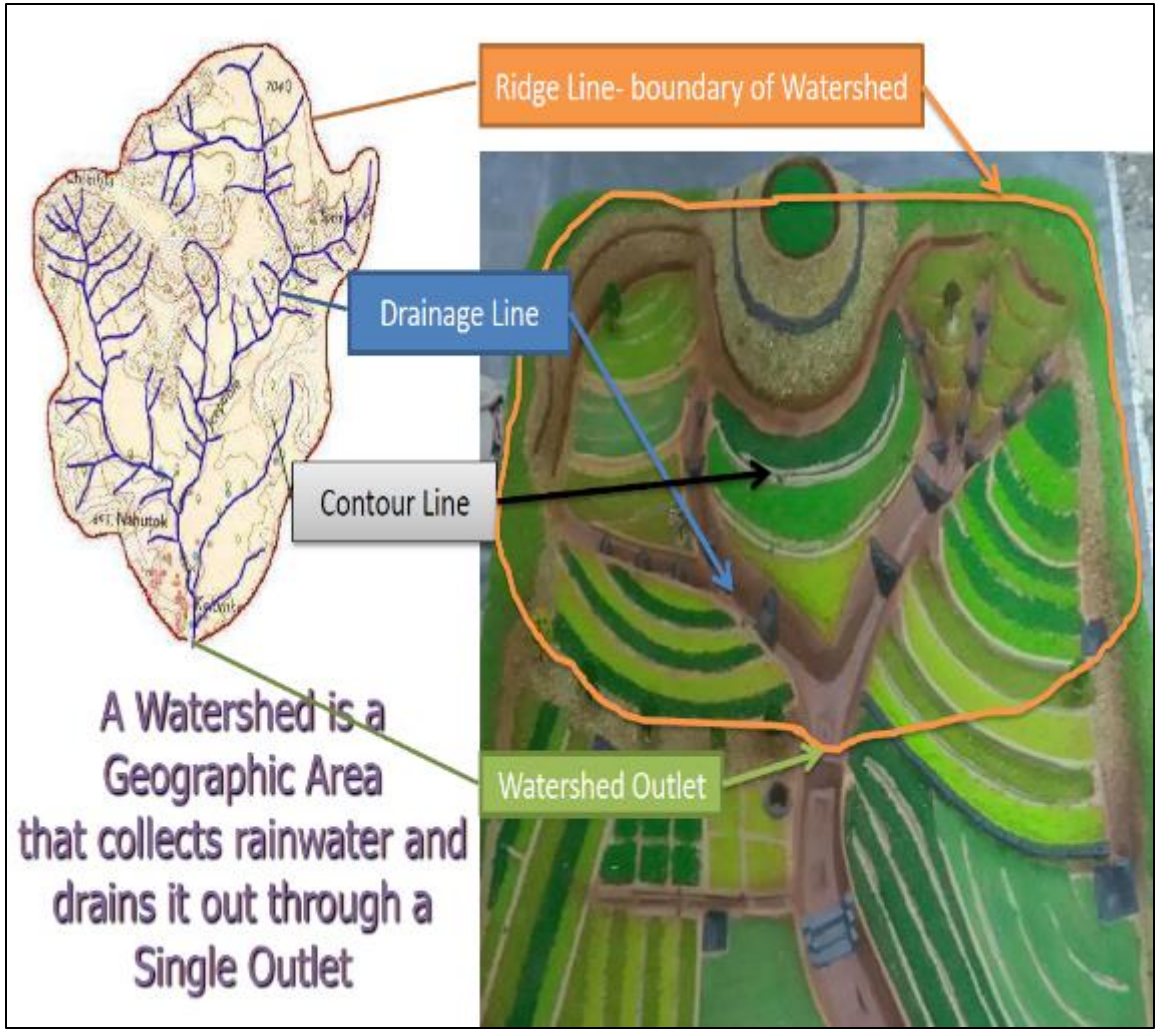
- India, ranked #13 (Out of 17) on Aqueduct's (WRI) list of "extremely highly" water stressed countries
- **3 times more** of vulnerable population than in the other 16 countries together.
- 21 major cities in India are racing to **reach zero groundwater** levels

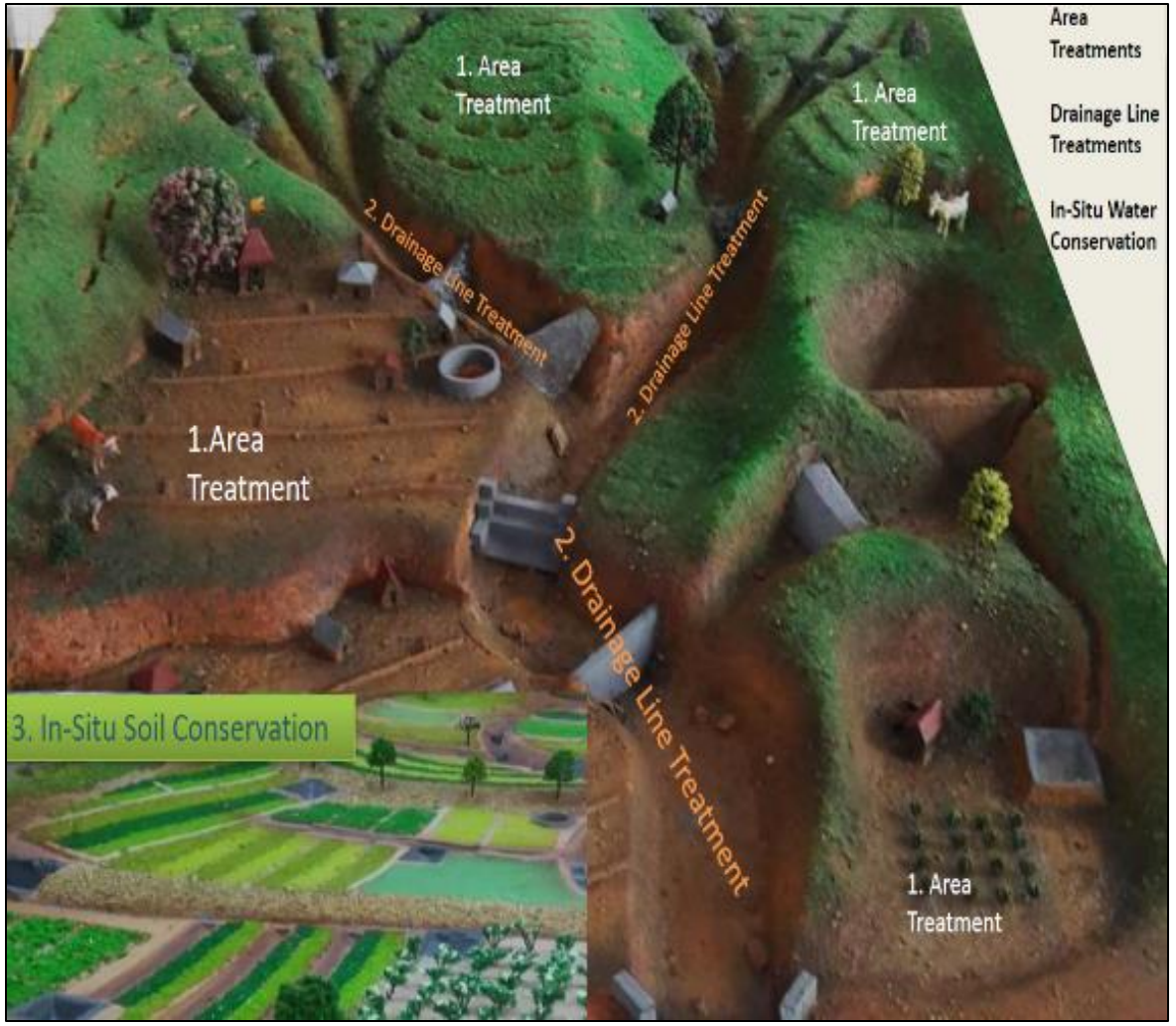
Ways to Achieve Water Neutrality

- On-site: Reduce own water consumption (but it cannot become zero!)
- On-site: Recycling of treated water (Cost is high!)
- On-site: Rainwater harvesting at own premises (It cannot cover 100% of need)
- Off-site: Collaboration with Municipal corporation for recycling of treated wastewater
- Off-site: Rain water harvesting (Urban / Rural)

Average rainfall in Telangana is 700 mm so we need to achieve maximum water conservation in a cost-effective manner. Project sustainability through community participation.

Watershed & Its Management



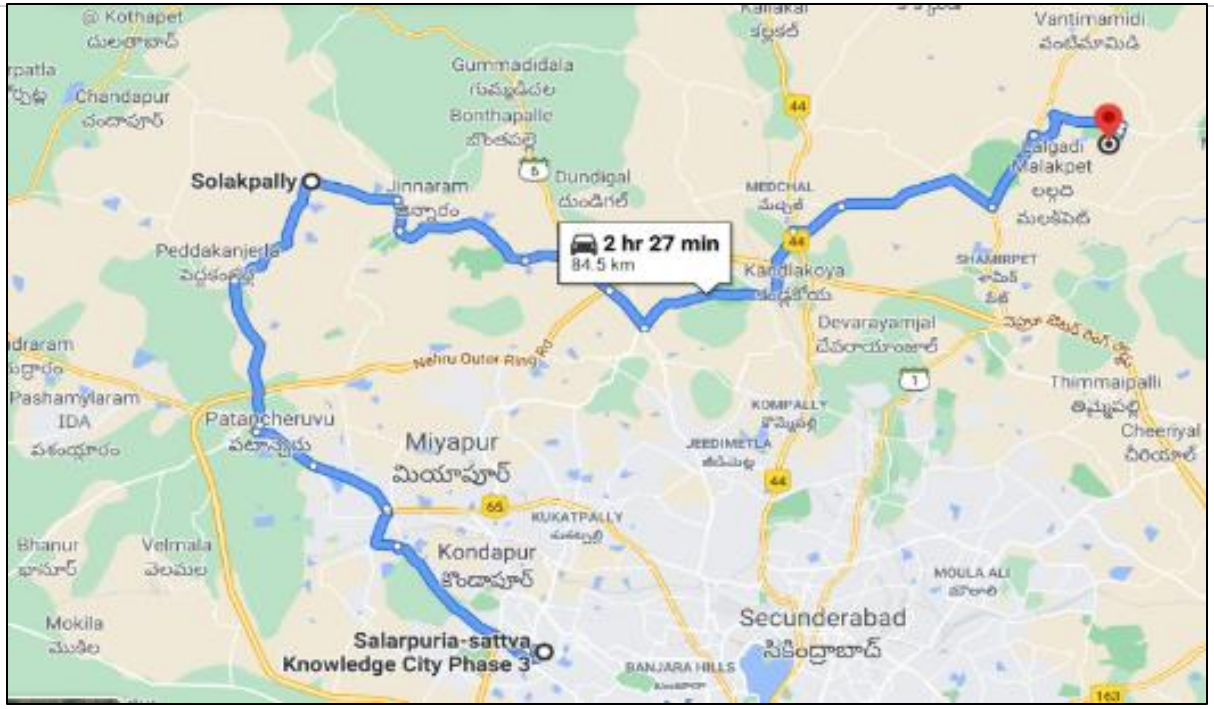


Courtesy to google for pictures

Community Watershed Project Overview

In alignment with our strategic priority of building trust with society and environment sustainability goal of water neutral community watershed project launched on March 22, 2021 (World Water Day)

- **Location Selection –** River basin where the organization operates or river basin where there are shared water users
- **Project Location:** – Amdoor Immanagar, Miyagiguda, Rallekathwa, Solakplly, Rallekathwa Thanda in Jinnaram Mandal of Sangareddy District of Telangana. Distance from Novartis own locations is 50 km and within close proximity of operation of key suppliers
- **Project area:** Approx. 2000 hectares
- **Funding period:** 4 years



Google map indicating Novartis offices and Project Location

Novartis inaugurates innovative watershed project in India to increase water availability | Novartis

To Lead by Impact: Building an environmentally sustainable business | Novartis India

Project 4E Approach

Economy

Increasing the income of farmers through sustainable agriculture and agribusiness for small and marginal farm holders including women.

Agricultural productivity improvement through "Lean Farming" addressing "Seed – Grain" and "Soil – Market" value chain,, Frontline Demonstrations, Promoting Agri-business and agri allied sector enterprises etc.,

Environment

Strengthening and conserving the natural resources of rural ecosystem through Watershed and NRM (reclaiming ecosystems).

Watershed development, Afforestation, Organic agriculture, lean farming, agro and bio-diversity conservation, WASH initiatives etc.,

Education

Strengthening the human asset in the agriculture and rural sector through need based and demand-driven training and capacity development programmes

Training and building capacities of farmers, women farmers, students, civil societies, government agencies and other stakeholders, entrepreneurship development programmes, etc.,

Empowerment

Creating dynamic, vibrant and sustainable rural communities who work in the spirit of cooperation, equity, equality and collective ownership. Promoting and nurturing various community-based institutions like Farmers Producer Companies, SHG Federations, Farmers Cooperatives, Water User Groups for collective decision making and action for institutional sustainability

Courtesy to NAF for slide

Community Watershed Project & SDGs

Goal 1: No Poverty

Goal 3: Good health and well-being

Goal 4: Quality education

Goal 5: Gender equality

Goal 6: Clean water and sanitation

Goal 8: Decent work and economic growth

Goal 11: Sustainable cities and communities

Goal 12: Responsible consumption and production

Goal 13: Climate action

Goal 14: Life below water

Goal 15: Life on land

Goal 17: Partnership for the goals

Key Business Benefits

Reporting in CEO water mandate and covered under Corporate Social Responsibility

Education

- Role model for sustainable sourcing with proactive approach
- Pilot for scalable projects

Healthcare

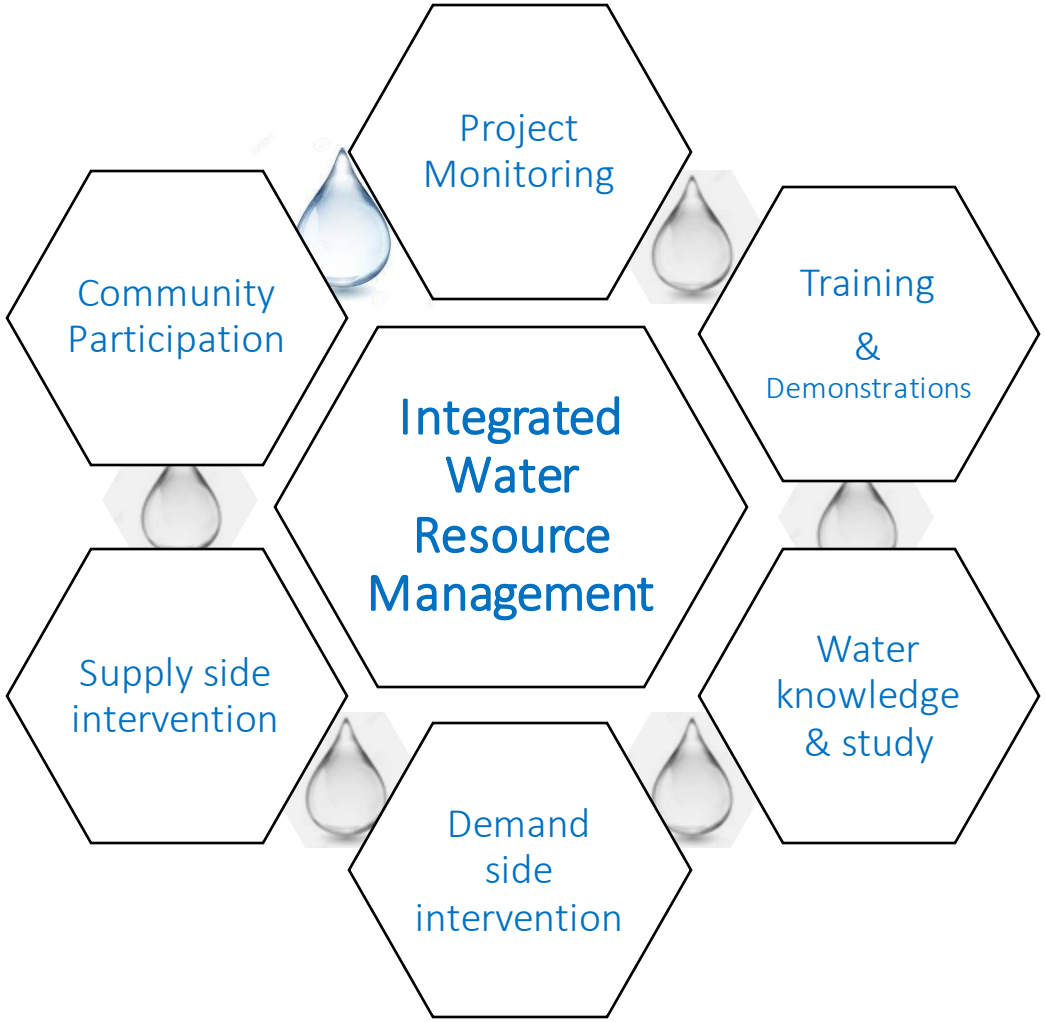
- Support to Healthy Family program of Novartis
- Business continuity

Environment

- Progressive step towards water neutrality
- Supporting Carbon Neutrality Goal by carbon sequestration

An Integrated Approach

- Selection of NGO, Selection of Location
- Detailed Project Report (DPR)
- Knowledge-based Entry Point Activity (KB-EPA) for Building Rapport with the Community
- Formation of Community-based Organizations (CBOs)
- Supply and Demand side interventions
- Livelihood Support
- Capacity Development of community
- Monitoring of project impacts and external assurance (if required)
- Maintenance fund Creation
- Handover Project to Community



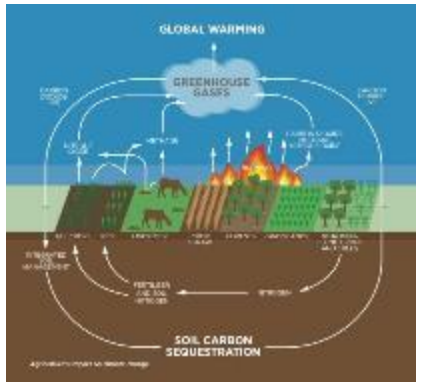
The Watershed Benefits

No.	Description of Benefit	Expected output
1	Creation Water Storage capacity (m3)	50000
2	Number of water storage structures by type	5 Ponds
		8 Check Dams
3	Increase in ground water level	Existing level + 10ft over 3 years
4	Number of trees planted	3000 Nos. with 90% survival rate

No.	Description of Benefit	Expected output
5	Area covered under Afforestation through tree plantation	20000
6	Soil health check up	100% landowners
7	Total area coverage benefitted due to interventions	2000
8	Training hours by training topics	7500

The Watershed Benefits

No.	Description of Benefit	Expected output
9	New area of farm land brought under cultivation	
10	Agriculture productivity	Paddy 28 quintal/acre
11	Crop and season diversification	3 crops
12	Increase in farmer income	Rs. 5000/acre



No.	Description of Benefit	Expected output
13	No. of farmer families benefited	1030
14	New farmers undertaking Agriculture as their occupation	-
15	Increase in crop intensity	25%
16	Carbon Sequestration	-

Note – Images are for illustrative purpose only They are not actual pictures from project

Cost/liter less than candy

Other benefits in same cost:

- Support to Healthy Family Program by providing safe drinking water and sanitation facilities to school children
- Carbon Sequestration
- Build Trust with society
- Water savings by farmers (reduction in water usage for crops)

Note –

1. Only surface water collection is considered for cost calculation.
2. Ground water level increase and subsequent water storage is not considered
3. Project life is minimum 20 years hence project benefit is for 20 years, spend is one time

NGO Supporting Novartis

National Agro Foundation

Web address - National Agro foundation

About Us

National Agro Foundation (NAF) was established in the year 2000 by The Architect of Indian Green Revolution, **Shri C Subramaniam**, and was further nurtured by Former President of India **Dr A P J Abdul Kalam** (as Chairman of NAF Governing Council), for comprehensive rural development with prime focus on transforming the direction of the Indian agriculture **from "production oriented" to "market-oriented"** or in the words of Our Founder **from 'seed to grain' to 'soil to market'**.

Our Vision

To create a "Healthy, Literate and Prosperous Rural India"

Our Mission

"Creating replicable models of prosperous rural clusters through ecologically safe, environmentally sustainable farm and non-farm sector activities, natural resource management, rural enterprises and human resource development by networking various stakeholders through mutually beneficial partnerships."

Achievements (as on date)

Project implementation period is 3 years. Project started in January 2021

EPA Activities at schools–

Water Purifier -4

Toilets -2

Hand wash basin -4

Sports Kit – 4

Basic Furniture set -4

Automatic weather Station

No. of Beneficiaries –

130 school children

NRM Activities –

1 pond rejuvenation

6 check dams construction

Channel clearance - 10500 m3

Additional water storage capacity generated 16477 m3

Demand Side Activities –

Training > 400 man-hours

Front line demonstration -6

Pest Light Traps -6

Soil Health Check Up-350

Livelihood Support -5 Women

Community Interaction



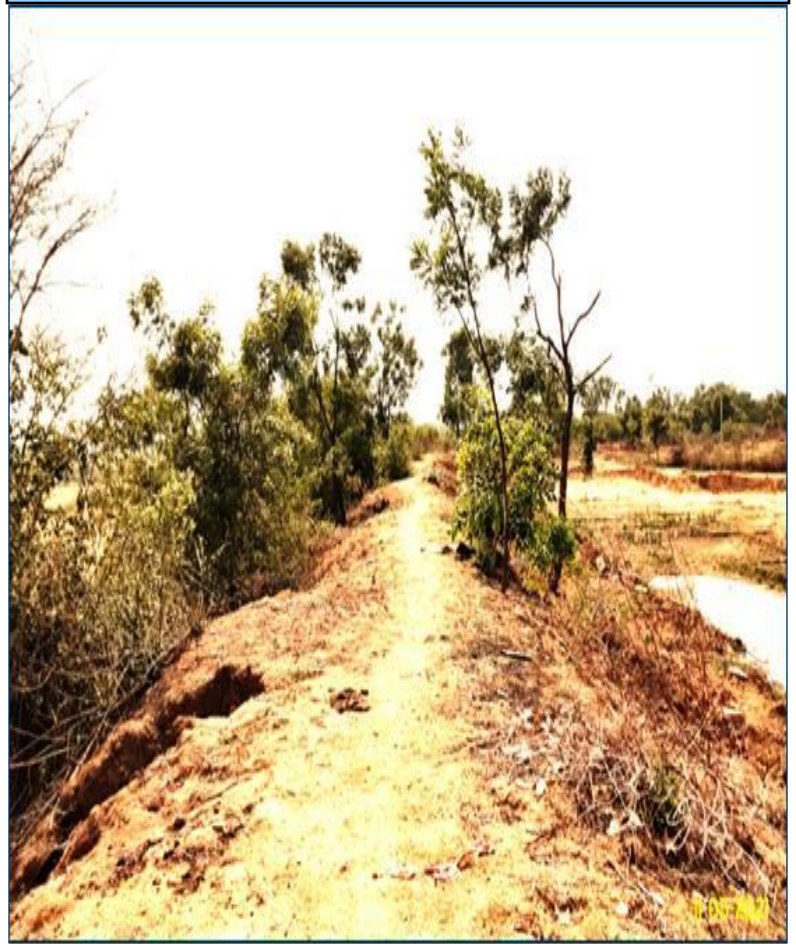



Inauguration Program – World Water Day

Entry point activities

Pond Rejuvenation

Bund Strengthening before



Community Handover

Bund Strengthening after

Check Dam Construction

Channel Desilting

Capacity Building for Farmers

hen Empowerment

Community Engagement Program


THANK YOU

QUIZ / POLL

- Call for an action –
  - Do you like the Approach – Yes/ No/ No comment

  - Would you be willing to be part of this project. – Yes/ No/ No comment
    How you would like to part of it – Self initiation/ Collaborate with PSCI or Novartis

  - What part of project you liked most
    - Entry point activities (sanitation facilities for schools)
    - Natural resource management activities (Water recharge and storage)
    - Water demand side activities (water saving techniques for farming)
    - Livelihood support (Women Self help group support)
    - Integrated approach (Water recharge, water saving & engaging community, women empowerment , sanitation for schools)

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

Air Emission & Control Measures in Pharmaceuticals Industry

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SPEAKER BIO

- Name: **Sushil Kumar Kharkwal**
- Job Title: Corporate Head - EHS
- Organization: Alembic Pharmaceuticals Ltd
- Organization Profile: Pharmaceuticals, API and Formulations
- Contact : +91 99096 99111 (sushil.kharkwal@alembic.co.in)

- Speaker is a post graduate in Chemical Engineering from IIT Roorkee. He has around 28 years of experience in safety and environment field. Worked as Corporate Head EHS in his previous roles in PI Industries Limited and Atul Limited. Other important companies he has worked are, Jubilant Lifesciences, UPL and Gujarat Ambuja Cements.

Alembic Pharmaceuticals Limited

Touching Lives over 100 years…

Corporate overview

www.alembicpharmaceuticals.com

Alembic Pharmaceuticals Limited

Established in 1907
Location : Vadodara, Gujarat, India, having 9 facilities
Consolidated annual revenue above USD 737 million
Listed on Stock Exchanges (BSE & NSE); approx. market cap of USD 2.48 Billion*

Branded Formulations

- Established across 17 therapeutic segments
- Leaders in Macrolides
- 5000+ sales force & marketing team

Global Generics

- Presence across North America, Europe, APAC, LatAm, MENA
- Market specific Products & Strategy
- Growing at 15% CAGR for last 5 years

Active Ingredients

- Leading supplier of generic APIs globally
- Customers include generic & innovator companies
- Offering 100+ APIs

AGENDA

- VOC Emission and Control
- Fugitive Dust Emission Control
- Stack Emission Control
- Quantification of VOCs
- Emission Monitoring
- Emission Standards for Pharma Industry

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

VOC Emission and Control

1. Types and Source of VOC Emission
2. VOC Emission Control from Point Sources
3. Fugitive VOC Emission Control Measures

Types & Sources Of VOC Emission

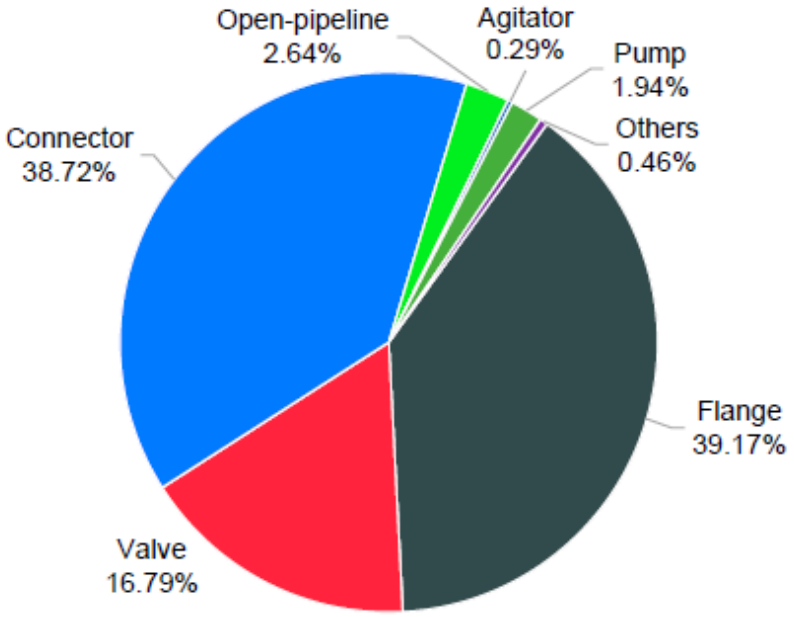
- VOC (Volatile Organic Compounds) are organic chemicals that have a high vapour pressure at room temperature. In industrial settings, all solvents contribute to VOCs but there could be other sources.
- Typical sources of VOC emission is categorized in two types:
  1. Point Source (Vent) Emission
  2. Fugitive Emission

1. VOC Emission from Point sources :
   - Any open-ended pipe or stack that is vented to the atmosphere either directly, through a vacuum producing system, or a tank associated with the regulated equipment is known as process vent.
   - Process vents are associated with:
     - Distillation
     - Fractionation
     - Thin-film evaporation
     - Solvent extraction

Types & Sources Of VOC Emission

2. Fugitive VOC Emission

- Fugitive sources are not intended vents but are spread over many abnormal activities.
- Fugitive VOC emissions are found to be caused by leaks from pipelines, centrifugal separation, filtration, vacuum, solvent recovery, and drying equipment; of these, pipelines are found to be particularly significant.



Contribution of different types of equipment to leaks

VOC Emission Control from Point Sources

- Acid scrubber
  - An acid scrubber works at low pH levels
  - Used for control of

    NH_3, Amines, Alkali reacting components
- Alkaline scrubber
  - Scrubbing media is alkaline, mostly caustic soda
  - Used for control of

    HCl, SO_2, Cl_2, Phenols, Organic acids
- Venturi scrubber
  - Additional turbulence is generated in these scrubbers by high gas velocity, for higher efficiency.
  - Used when OEL values are low or fine dust need to be controlled.

Fugitive VOC Emission Control Measures

- Creating negative draft and connecting the vacuum system to scrubber.
- Use of chilling media (condensers)
- Close handling of the chemicals. Use of equalization lines
- Use of breather valves
- Use of Barrel pumps for liquid charging
- Use of Double mechanical seals
- PM of all material transferring equipment
- Use of LDAR technique.

Reactor vent connected with double condenser

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Fugitive Dust Emission Control

Fugitive dust emission control

- AHU (Air Handling Unit)
  - AHU regulates air quality mostly though air-conditioning (HVAC) system.
  - Number of air changes should be decided based on OEL values of chemicals.
- HEPA Filter
  - HEPA (high-efficiency particulate air) filters capture pollen, dirt, dust, moisture, bacteria , virus, and submicron liquid aerosol.
- PTS System for Charging of Solid materials
  - Powder Transmission System (PTS) not only stops fugitive dust emission but also effective control against dust explosion.
  - Can dispense both dry and wet powders and granules in a safe and contained manner.
- Dust Collectors
  - Normally use bag filters, with or without cyclonic action

PTS

Dust collector

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Stack Emission Control

Stack Pollution Management

- Control Through height (dispersion)
  - Adequate height (minimum 30 meters) is mandatorily required for Boiler and DG stack
  - If the capacity of boiler is high or SO_2 load is high, height is to be increased with formula $H=14Q^{0.3}$, where Q is SO_2 load in kg/hr. (As per CPCB guidelines)
- Wet Scrubber
  - Normally water is used for capturing dust or acidic gases
  - Has associated problems of corrosion, choking, disposal of high TDS media, solid disposal
- Bag Filter
  - Used for control of particulate matter
- Lime injunction
  - Used for control of SO2 in flue gases
  - Lime powder can be injected after furnace, followed by bag-filter, or
  - It can be mixed with fuel (coal) at the feed

Wet scrubber – ventury type

Bag Filters

Online Continuous emission monitor (CEMS)

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Quantification of VOCs

Quantification of VOCs

- Quantification of VOCs is not a easy task. We can adopt two methods for quantification:
  - Mass balance
  - Actual Measurement (Given in next section)
- Solvent losses in any particular area need to be measured. These losses can be from:
  1. Material transfer
  2. Losses from glands/ flanges
  3. Vents/ centrifuge openings
  4. Drums/ storage tanks/ intermediate vessels
  5. Driers

- Cumulative losses can be divided with total room volume and air changes to arrive at a theoretical VOC value.

Typical points of solvent losses

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Emission Monitoring

1) Workplace Monitoring

Workplace Monitoring For Exposure Control

- OEL (Occupational Exposure Limit) of the chemicals being handled should be established.
- Monitoring of chemical at workplace should be conducted for establishing work place concentrations.
- Workplace concentration should be checked
  - at source
  - At environment, and
  - At recipient
- If OEL values are very low (potent drugs, Onco drugs, peptides, etc) controls like PAPR or Isolators should be used.

Handy Air sampler
Source monitoring)

VOC Meter
(Work place monitoring)

Monitoring with Dosi Meter
(Recipient monitoring)

FORM NO. 37

(Prescribed under Rule 12-B)Register containing particulars of monitoring of working e

Section 7-A(a)(e).

Industry:	**Alembic Pharmaceuticals Limited (API-II)**	**Ref. No.:**	20
Location:	Vill: Panelav, P.O. Tajpura, Tal: Halol, Dist: Panchmahal	**Report Date:**	16
		Analysis Date:	13
Authorised Person:	Mr. Kashyap Raval	**Analysed By:**	G
Additional Information: Sample collection and analysis by: Name: Mr. Girish M. Desai Qulification: M.Sc. Organic Chemistry Organisation: Prakruti Environmental Engineers		**Receipt Date:**	12
		Receipt Time:	18
		Received By:	Vi
		Collection Date:	11
		Collection Time:	14

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Emission Standards For Pharmaceutical Industries

1) Existing Emission Standards
2) Proposed Emission Standards

Emission Standards

Air Emission Standards:

- Ministry of Environment has notified new air emission standards for Phamaceutical Industries on 06.08.2021.
- For Boilers and Incinerators, separate standards are available
- Mandatory installation of Continuous Emission Monitoring System (CEMS) for more than 8 MT capacity boilers
- Use or scrubbers or lime injection for coal fired boilers
- FO can not be used

Process Stack Emission

Parameters	Limiting Value for concentration (mg/Nm^3)
Chlorine	15
Hydrochloric Acid Vapour	35
Ammonia	30
Benzene	5
Toluene	100
Acetonitrile	1000
Dichloromethane	200
Xylene	100
Acetone	2000

The total losses of solvent should not be more than 3% of the solvent consumed.

National Ambient Air Quality Standards

Pollutant	Time Weighted Average	Concentration in Ambient Air		
		Industrial Area	Residential, Rural and other Areas	Sensitive Area
Sulphur Dioxide (SO_2)	Annual Average*	80 µg/m^3	60 µg/m^3	15 µg/m^3
	24 Hours Average**	120 µg/m^3	80 µg/m^3	30 µg/m^3
Oxides of Nitrogen as NO_2	Annual Average*	80 µg/m^3	60 µg/m^3	15 µg/m^3
	24 Hours Average**	120 µg/m^3	80 µg/m^3	30 µg/m^3
Suspended Particulate Matter (SPM)	Annual Average*	360 µg/m^3	140 µg/m^3	70 µg/m^3
	24 Hours Average**	500 µg/m^3	200 µg/m^3	100 µg/m^3
Respirable Particulate Matter (Size less than 10µm) (RPM)	Annual Average*	120 µg/m^3	60 µg/m^3	50 µg/m^3
	24 Hours Average**	150 µg/m^3	100 µg/m^3	75 µg/m^3
Lead (Pb)	Annual Average*	1.0 µg/m^3	0.75 µg/m^3	0.50 µg/m^3
	24 Hour Average**	1.5 µg/m^3	1.0 µg/m^3	0.75 µg/m^3
Carbon Monoxide (CO)	8 Hours Average**	5.0 mg/m^3	2.0 mg/m^3	1.0 mg/m^3
	1 Hour Average	10.0mg/m^3	4.0 mg/m^3	2.0 mg/m^3
Ammonia (NH_3)	Annual Average*	0.1 mg/m^3		
	24 Hour Average**	0.4 mg/m^3		

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Science of Safety

Respiratory Protection - Selection & Fit of RPE

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AGENDA

Basics of Respiratory Protection

Elements influencing performance of RPE

Science of Fit

Q&A

SPEAKER BIO

- Name: **Giridhar M**
- Job Title: **India Leader, PSD Application Engineering & Regulatory Affairs**
- Organization: **3M India Limited**
- Organization Profile: www.mmm.com
- Contact: rmgiridhar@mmm.com

- 20+ years with 3M Personal Safety Division working with various industries in the area of occupational health & safety
- Involved with many organizations in implementing appropriate PPE programs. Member of International Society for Respiratory Protection
- Engaged with several industry associations and regulatory organizations to provide technical expertise in the area of personal protective equipment.
- Led new product launches such as respirators, welding products. Was part of “3M Safety on Wheels” - Workplace health & safety awareness program in Indian industries

The Science of Safety

Respiratory Protection

Selection & Fit of RPE

Giridhar M

Sep 23, 2021

Opening Points

- This presentation is based on various regulatory requirements as of Apr, 2020. State or other country requirements may be different. **Always consult User Instructions and follow local laws and regulations.**

- This presentation contains an overview of general information and should not be relied upon to make specific decisions. Completing this program does not certify proficiency in safety and health.

- Information is current as of April 2020, and requirements can change in the future.

- This presentation should not be relied upon in isolation, as the content is often accompanied by additional and/or clarifying information or discussion.

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Science.
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Improving lives











Serving our customers through four business groups

Safety & Industrial

Accelerating safety and industry performance by serving the industrial, electrical and safety markets.

Transportation & Electronics

Moving transportation and a connected world forward by serving automotive and electronic OEM customers.

Health Care

Connecting people, insights, science and technology to make better health possible around the world by serving the health care industry.

Consumer

Innovating to simplify life and work by serving global consumers.

$32.1 B
Global Sales

96,000+
Talented Minds

70
Countries

4
Business Groups

51
Technology Platforms

126,416
Patents awarded in Company history

3M in India: 30+ years of Innovation

Established in
1988
Publicly owned
Subsidiary since
1991

INR 3032 crore
sales turnover for 3M India Limited consolidated as of March 31, 2020

6 Branch Offices
4 Manufacturing facilities
3 Innovation Centers

1300+
employees

100+ R&D
Professionals


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Equipment

Present day context

Healthcare

Public safety

Industrial safety

https://www.3m.com/3M/en_US/worker-health-safety-us/safety-resources-training-news/science-of-safety/

Evolution of Personal Protective Equipment




Image source:

https://www.piqsels.com/en/public-domain-photo-olsbg
https://instabusters.net/photo-video/CAPOxF7JZHS
https://ohsonline.com/Articles/2007/01/01/PPEvolution.aspx

Importance of workplace health & safety

Acute hazards

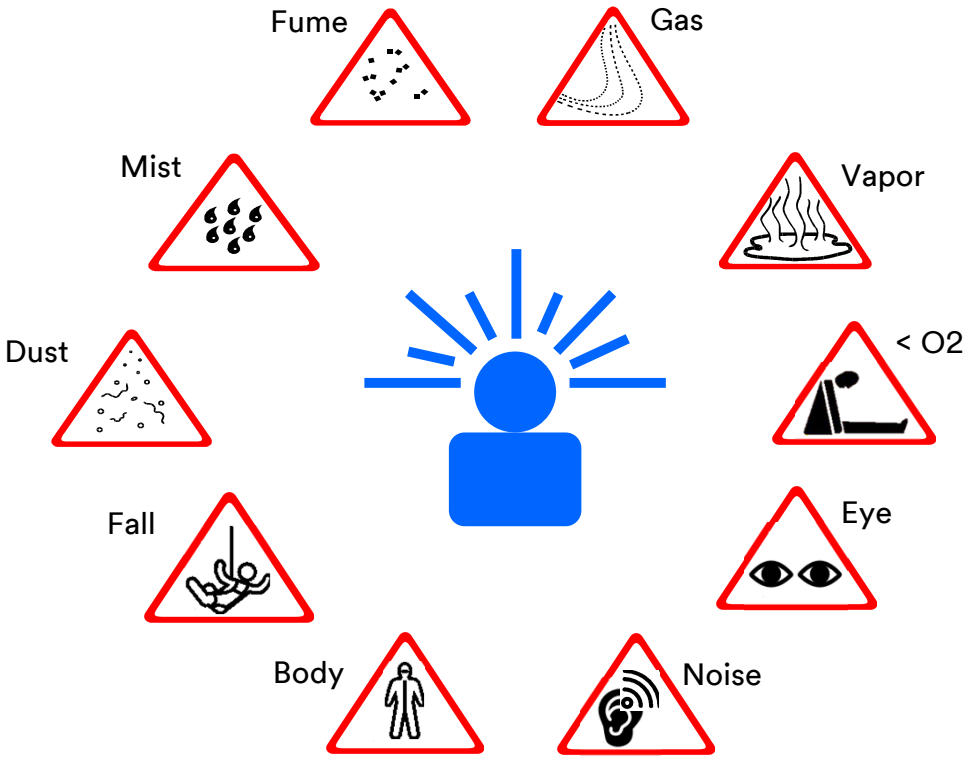
Hazards that can potentially cause immediate injuries.

- falling objects, flying particles

Chronic hazards

Hazards that can potentially cause adverse long term health & safety effects.

- *welding fume, chemicals*



Cost of lack of Health & Safety at workplace

Compensation

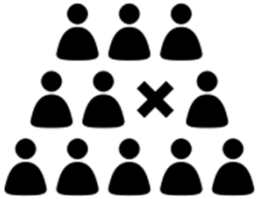
Insurance

Re-training

Safety is not a cost, Accident is.

Re-hire

Absenteeism

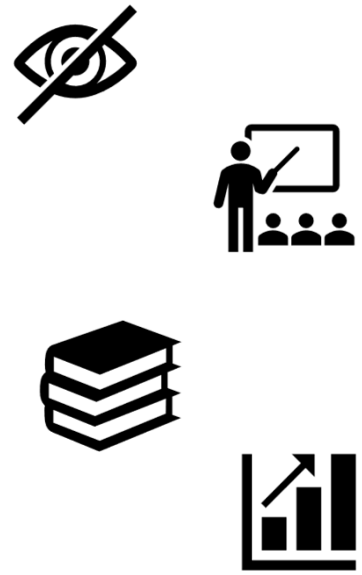


Cost per component

Productivity

Challenges faced by safety & manufacturing managers

- **Awareness** about workplace safety among employees
- **Knowledge** on appropriate Personal Protective Equipment (PPE) to be used at workplace
- Knowledge about **Regulatory** need & how to comply
- Employees do not use PPEs provided to them- **behavioral ??**
- How can safety enhance **productivity**



Establishing PPE program & provides an on-going training in usage & maintenance of PPE

What influences PPE adoption/implementation

Involve the users, the employees; build awareness – "take their safety, personally"

- Meet or exceed regulatory requirement
  - Conforms to India/global and "relevant" authority
  - Certified for product performance

- Fits the user
  - PPEs are Fit tested on the user (eg. Respirators, hearing protectors)

- User comfort
  - Motivates users to wear them for full time of exposure
  - Easy donning & doffing

- Training in usage, maintenance & disposal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Respiratory
Protection
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Masks And Respiratory Protection Types

Face covering	Surgical mask	Filtering Facepiece (Disposable)	Reusable Respirator	Powered & Supplied Air	Self Contained Breathing Apparatus - SCBA
Loose	**Loose**	**Tight**	**Tight**	**Loose**	**Tight**
					
					

Helps reduce wearer's exposure to airborne particles

Components can be disinfected & reused

Mask Vs Respirator

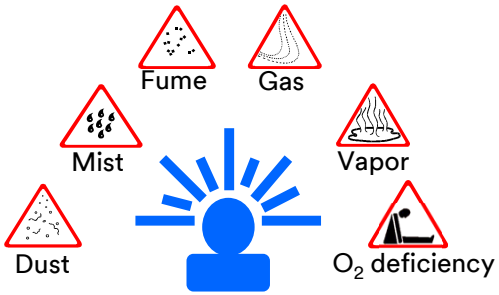
https://multimedia.3m.com/mws/media/1794572O/surgical-n95-vs-standard-n95-which-to-consider.pdf

	General Mask	Surgical Mask	Standard N95 or equivalent Respirator	Surgical N95
Construction				
Use in				
Fit				
Approval / Certification	Unknown	**FDA**	**NIOSH, CE, BIS**	**NIOSH, FDA**

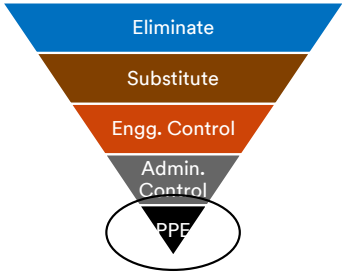
This table provides general information concerning the products shown. Always read and follow all user instructions and applicable guidance.

Respirator selection

1 Identify hazard & measure concentration



2 Apply hierarchy of controls

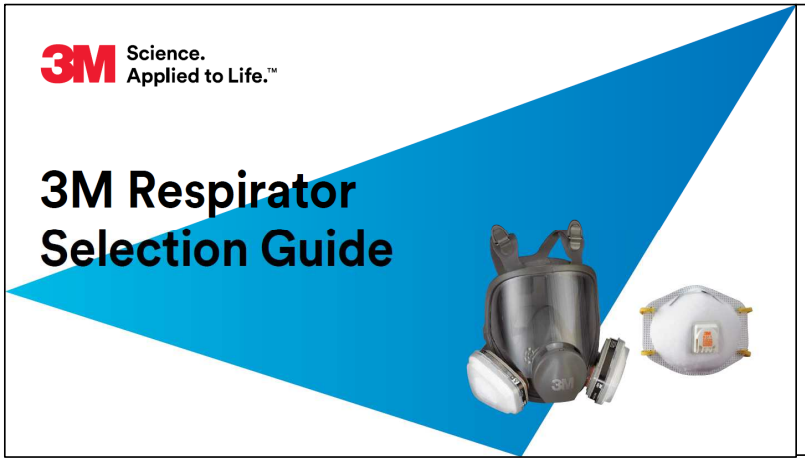


3 Calculate Hazard Ratio

$$\frac{\text{Workplace concentration}}{\text{Permissible level}}$$

4 Select Respirator based on APF

- Disposable Respirator
- Reusable Respirator
- P&SA Respirator
- SCBA Respirator



NOTE: See important warnings, definitions, and explanation of column headings and abbreviations starting on page 1

15

Chemical Name CAS #	Synonym	IDLH (ppm)	OEL (ppm)	Respirator (Exposures < both APF x OEL and IDLH)	Comments
Acetaldehyde 75-07-0	Acetic aldehyde, Ethanal	10000	TWA=200 (OSHA) C=25	(F)OV (F)MG	Multigas cartridge recommended for longer service life
Acetamide 60-35-5	Ethanamide		TWA=1 (inhalable fraction and vapor)	OV/N95	See comment D on page 8
Acetic acid 64-19-7	Ethanoic acid, Glacial acetic acid, Methane carboxylic acid, Vinegar acid	1000	TWA=10 STEL=15	(F)OV/AG	
Acetic anhydride 108-24-7	Acetic acid anhydride, Acetyl oxide, Ethanoic anhydride	1000	TWA=1 STEL=3	(F)OV	
Acetone 67-64-1	2-Propanone, Dimethyl ketone, Ketone propane	20000	TWA=250 STEL=500	OV	Short service life. 3M 3530 Monitor
Acetone cyanohydrin 75-86-5	2-Cyano-2-propanol, 2-Hydroxy-2-methyl propanenitrile, 2-Methyllactonile, 2-Propane cyanohydrin, a-Hydroxy isobutyronitrile	22000	TWA=2 (AIHA) STEL=5 (AIHA) C=5 mg/m³ (as CN) -skin-	OV	
Acetonitrile 75-05-8	Cyanomethane, Ethane nitrile, Ethyl nitrile, Methanecarbonitrile, Methyl cyanide	4000	TWA=20 -skin-	OV	3M 3530 Monitor

Hazard Ratio

1.

Chemical Name CAS #	Synonym	IDLH (ppm)	OEL (ppm)	Respirator (Exposures < both APF x OEL and IDLH)	Comments
Ammonia 7664-41-7	Anhydrous ammonia	500	TWA=25 STEL=35	(F)AM	Irritation also provides warning

2.

Respirator Selection Form

Chemical Name	Air Concentration	IDLH	OEL	Hazard Ratio	Respirator Type
Ammonia	150	500	25	6	
Respirator Selected:					

3.

$$= \frac{\text{Airborne Contaminant Concentration}}{\text{Occupational Exposure Limit}} = \frac{150}{25}$$

Select a respirator that provides a protection factor of at least 6

Assigned Protection Factor

Assigned Protection Factor (APF) means the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the eployer implements a continuing, effective respiratory protection program as specified by this section [meaning 29 CFR 1910.134].

Maximum Use Concentration (MUC) means the maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator and, is determined by the assigned protection factor of the respirator or class of respirators and the exposure limit of the hazardous substance.

Table A. Assigned Protection Factors[5]

Type of Respirator[1,2]	Quarter Mask	Half Mask	Full Facepiece	Helmet/ Hood	Loose-Fitting Facepiece
1. Air-Purifying Respirator	5	10[3]	50	—	—
2. Powered Air-Purifying Respirator (PAPR)	—	50	1,000	25/1,000[4]	25
3. Supplied-Air Respirator (SAR) or Airline Respirator					
• Demand mode	—	10	50	—	—
• Continuous flow mode	—	50	1,000	25/1,000[4]	25
• Pressure-demand or other positive-pressure mode	—	50	1,000	—	—
4. Self-Contained Breathing Apparatus (SCBA)					
• Demand Mode	—	10	50	50	—
• Pressure-demand or other positive-pressure mode (e.g., open/closed circuit)	—	—	10,000	10,000	—

Assigned Protection Factor

Select a respirator that provides a protection factor of at least 6

APF	10	25	50	1000
If you are referring to OSHA 29 CFR 1926.1153 Table 1 **Find your APF**	**Disposable Respirators and Half Face Reusable Respirators**	**PAPRs and M-307 Respiratory Hardhat**	**Full Face Reusable Respirators (With quantitative fit test)**	**PAPRs and M-407 Helmet**
If you are doing an objective or scheduled assessment **Find your MUC***	 8210  6000  8210V  6500  8511  6500QL  9211+  7500	 TR-600 M-307   TR-300	 6000 FF  FF-400	 TR-600  M-407  TR-300
MUC*	**0.5 mg/m3 ▶**	**1.25 mg/m3 ▶**	**2.5 mg/m3 ▶**	**50 mg/m3 ▶**

Respirator selection

Occupational exposure banding, is a process intended to quickly and accurately assign chemicals into specific categories (bands), which correspond to a range of exposure concentrations designed to protect worker health. These bands are assigned based on a chemical's toxicological potency and the adverse health effects associated with exposure to the chemical. The output of this process is an occupational exposure band

For operations with insufficient and/or unverified engineering controls.

Table B

	Occupational Exposure Band (OEB)	
Activity	**OEB 1 and 2 (100 µg/m³)**	**OEB 3, 4 and 5 (< 100 µg/m³)**
Powder manipulation	Minimum required lab PPE, gloves	Minimum required lab PPE, gloves and appropriately fitted filtering facepiece respirator
Solutions and suspensions (no aerosols)	Minimum required lab PPE, gloves	Minimum required lab PPE, gloves, lab coat, safety glasses and spill trays
Potentially contaminated batch record handling	NA	Minimum required lab PPE, gloves, lab coat and safety glasses
Returned sample handling of broken or leaking presentations and uncoated tablets	Minimum required lab PPE, gloves	Minimum required lab PPE, gloves, lab coat and safety glasses

*** This chart offers suggestions only and should not be used without verifying that the Personal Protective Equipment (PPE) is appropriate for your unique situation.*

What do you choose?

Filtering Facepiece Respirators (Disposable Respirator)

3 configurations of respirators

Flat Fold

Cup shaped

3-Fold

Respirator categories

NIOSH- 42 CFR Part 84 test method*

	Aerosol Test Used for Classifying		
Minimum Efficiency	NaCl Non-Oil Aerosols	DOP* Includes Oil Aerosols	DOP Includes Oil Aerosols
95%	N95	R95	P95
99%	N99	R99	P99
99.97%	N100	R100	P100

N-series: Not for Oil

R-series: Resistant to Oil

P-series: Oil Proof

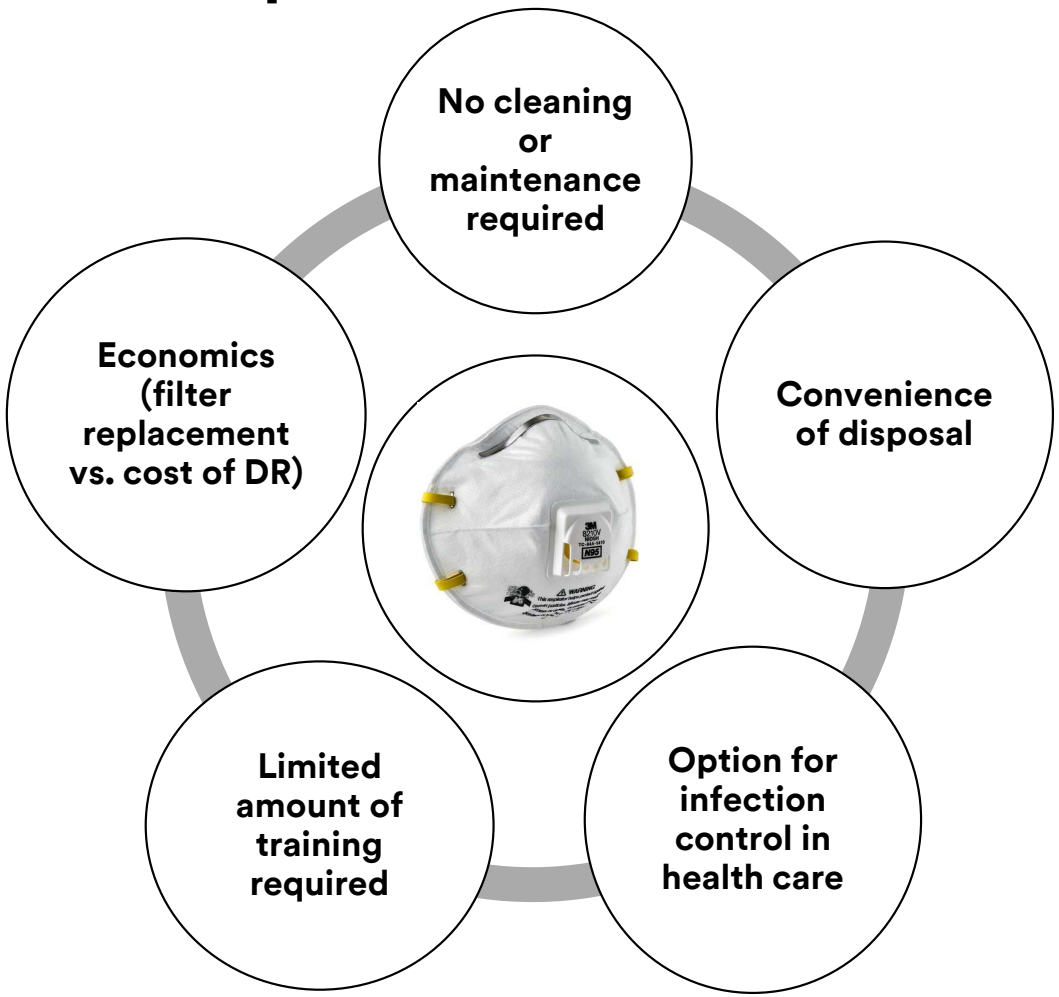
*May have time restrictions when oil aerosols are present. *All filters tested against a 0.3 micron particle. OSHA has specific standards for lead, cadmium, asbestos, arsenic and 4,4'-Methylenedianiline (MDA) requiring 100 level filters.

India standard – Particle Filters (IS 9473:2002) *

Filter	% NaCl Pen	% Paraffin Oil Pen
FFP1	20	-
FFP2	6	- 2
FFP3	3	1

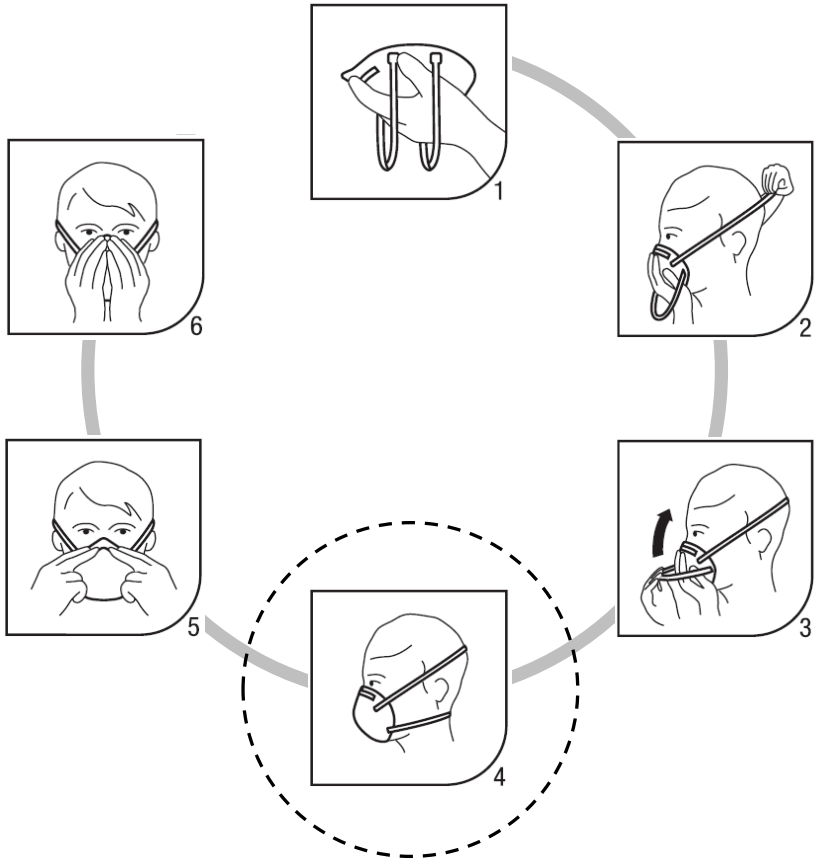
* Please refer to latest regulatory standards always.

Why Disposable Respirators?

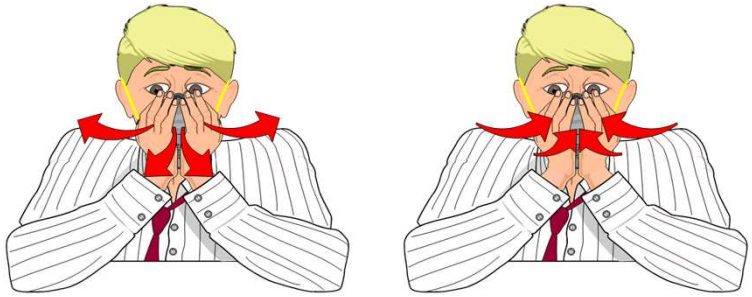


How to wear Disposable Respirators

Donning Steps



Face seal check



Positive Pressure *Negative Pressure*

- *To be conducted each time before entering contaminated environment*

Facial Hairstyles and Filtering Facepiece Respirators

Intended for workers who wear tight-fitting respirators

CLEAN SHAVEN ✓

STUBBLE ✗

LONG STUBBLE ✗

FULL BEARD ✗

FRENCH FORK ✗

DUCKTAIL ✗

VERDI ✗

GARIBALDI ✗

BANDHOLZ ✗

SOUL PATCH ✓

GOATEE ✓
(Careful! Chin hair may easily cross the seal)

CHIN CURTAIN ✗

EXTENDED GOATEE ✗

CIRCLE BEARD ✗

ANCHOR ✓

BALBO ✓
(Careful! Chin hair may easily cross the seal)

VAN DYKE ✗

IMPERIAL ✗

SIDE WHISKERS ✓

MUTTON CHOPS ✗

HULIHEE ✗

HORSESHOE ✓
(Careful not to cross the seal)

ZAPPA ✓

WALRUS ✓

PAINTER'S BRUSH ✓

CHEVRON ✓

HANDLEBAR ✓

PENCIL ✓ ✓

TOOTHBRUSH ✓

LAMPSHADE ✓

ZORRO ✓

VILLAIN ✓
(Careful not to cross the seal)

FU MANCHU ✗

ENGLISH ✗

DALI ✗

*If your respirator has an exhalation valve, some of these styles may interfere with the valve working properly if the facial hair comes in contact with it.
†This graphic may not include all types of facial hairstyles. For any style, hair should not cross under the respirator sealing surface.

Source: OSHA Respiratory Protection Standard
https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=12716

Further Reading: NIOSH Respirator Trusted-Source Webpage
https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource3fittest.html

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

2017

Reusable Respirators - RR

Half Face piece

Full Face piece

Applications

- Gas-Vapor exposure, in addition to particulates
- Need for higher protection factor (full facepiece)
- Reusable and replaceable components
- Can address compatibility concerns (eye, face protection)
- Tight face, P&SA respiratory option

Reusable Respirators – Facepiece & Cartridges (filters)





Organic Vapor	Acid Gas	OV/AG	Ammonia	Formaldehyde	Multi-Gas	Chlorine
						
6001	6002	6003	6004	6005	6006	6009

Particulate → Particulate + HF

2091	2096	2097	7093	7093C	5N11	501
						

Powered & Supplied Air Respirators

Powering Air Purifying Respirator

Supplied Air Respirator

Applications

- Particulates, Gas-Vapor exposure
- Pharma, Paint applications, Welding
- Need for higher protection
- Increased user comfort
- Address compatibility concerns (eye, face protection)

Differences between Disposable, Reusable, Powered & Supplied Air Respirator

Filtering Facepiece (Disposable) – DR

(+) Easy to wear
(+) No maintenance
(+) Storage convenience
(+) Certain models are approved for decontamination

(●) Limited protection DR<RR<P&SA
(●) Not suitable for Gas & Vapor
(●) Frequent replacement

Reusable Respirator - RR

(+) Limited maintenance (filters alone need to be replaced periodically)
(+) Longer lasting facepiece option
(+) Can be used in Gas & Vapor environment with relevant filters
(+) Higher protection than DR (Full facepiece)

(●) Periodic cleaning & maintenance
(●) Stocking of consumables
(●) Compatibility with other PPEs may be a challenge to some users
(●) Can be uncomfortable for some users

Powered & Supplied Air Respirator – P&SA

(+) Higher protection (>DR, >RR)
(+) Superior comfort due to constant supply of air
(+) Can be used in Gas & Vapor environment with relevant filters
(+) Longer usage with limited maintenance

(●) Storage convenience
(●) Maintenance of components
(●) Bulkier than DR, RR
(●) Batteries need to be charged periodically

* Images are representative. Comparison is for general understanding.
* Specific selection must be made based on workplace hazard.

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Selection of Respirators ☑

Science of Fit

What do Regulations say..

OSHA

https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA

1910.134(f)***Fit testing.*** This paragraph requires that, before an employee may be required to use any respirator with a negative or positive pressure tight-fitting facepiece, the employee must be fit tested with the same make, model, style, and size of respirator that will be used. This paragraph specifies the kinds of fit tests allowed, the procedures for conducting them, and how the results of the fit tests must be used.

1910.134(f)(2)The employer shall ensure that an employee using a tight-fitting facepiece respirator is fit tested prior to initial use of the respirator, whenever a different respirator facepiece (size, style, model or make) is used, and at least annually thereafter.

TC › ISO/TC 94/SC 15

ISO 16975-3:2017

Respiratory protective devices — Selection, use and maintenance — Part 3: Fit-testing procedures

Importance of Fit Test

- **No single type and size of respirator** fits everyone
- Wide range of **ethnic population**
- Wearers have different **anatomical facial features**
- **Real World** studies suggest difference between field and lab measurements
- May be required by **Law** in some countries

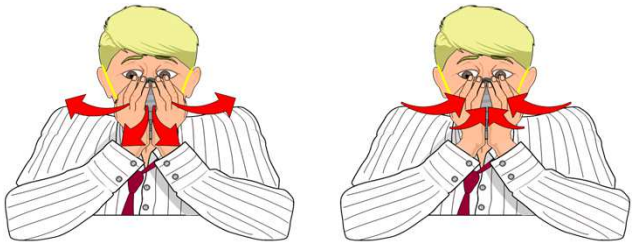
Fit testing needs to be conducted

- **prior to first use,**
- **whenever a different size, style, model or make is used and,**
- **at least annually thereafter**

Fit Check vs Fit Test – Respiratory Protection

Fit check

- ❑ Conducted by the wearer each time they put on PPE
- ❑ Gives an indication that the PPE is positioned correctly on the wearer
- ❑ Responsibility remains with the wearer
- ❑ Shows fitting errors



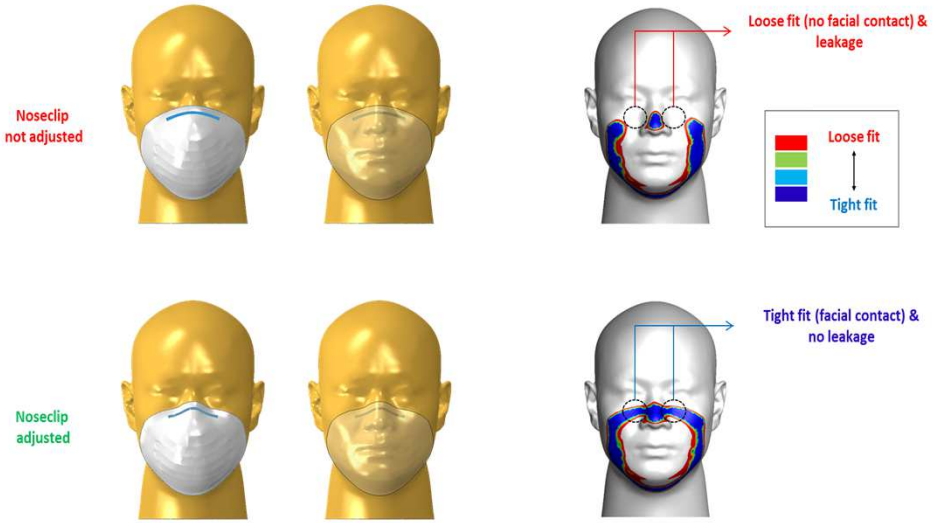
Positive Pressure *Negative Pressure*

•To be conducted each time before entering contaminated environment

Fit test

- ❑ Conducted each time a new model of PPE is selected
- ❑ Conducted by a competent person appointed by the employer
- ❑ Employers responsibility & may be required by law in some countries

Fit Testing



Fit Testing Methods

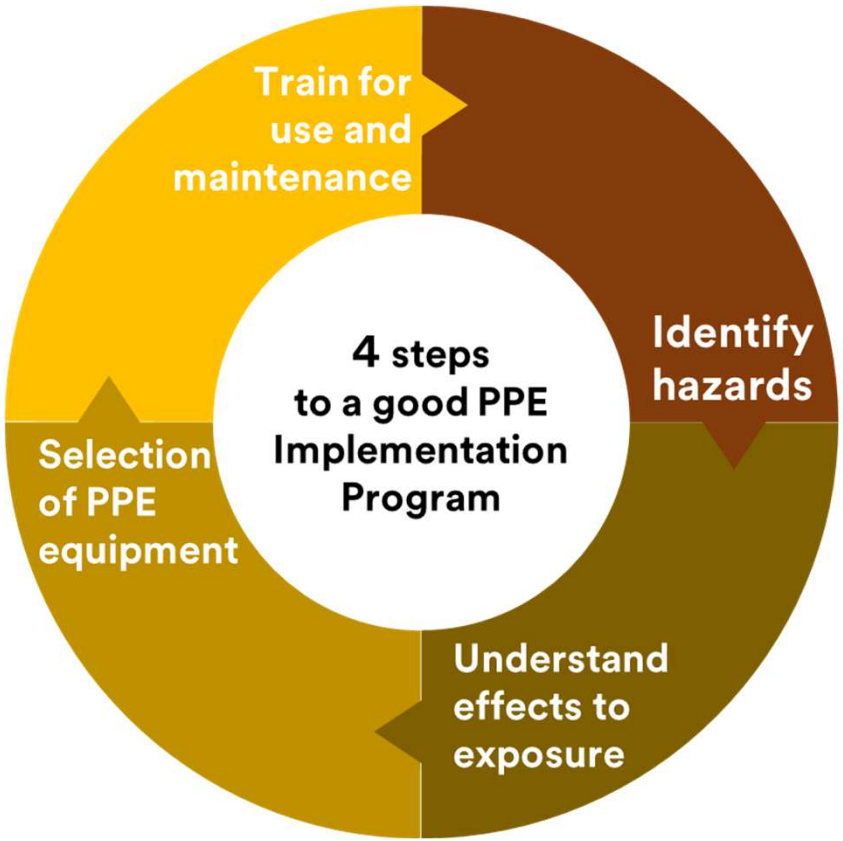
Qualitative (QLFT)

- Provides simple **Pass/Fail** based on wearer's subjective assessment or limited objective measurement e.g. pressure leak test for some custom moulded earplugs
- Wearer decides whether the PPE fits or not based upon taste/smell for filtering respirators, for example

Quantitative (QNFT)

- Provides a measured result
- Does not rely on the wearers perception
- Can be used on higher performing devices

In summary



- Occupational hazards may be unavoidable in many workplaces
- Most occupational injuries and adverse health hazards are preventable
- **Fit of Respirators** is as important as selection of them
- Involvement of employees, users is important for a sustainable, productive PPE implementation program

3M Personal Safety Division portfolio

Respiratory Protection

Hearing Protection

Fall Protection

Protective Eyewear

Head & Face Protection

Welding Safety

High Visibility Clothing

Connected Safety Software Solutions

Industrial Ergonomic Devices*

Protective Communications

Protective Apparel

3M | DBI SALA Fall Protection

3M | PROTECTA Fall Protection

3M | E·A·R Hearing Protection

3M | PELTOR™

3M | Scotchlite™ Reflective Material

3M | Speedglas™ Welding Safety

*distributor of ergonomic devices

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rmgiridhar@mmm.com

Thank You

Note: Business owners are responsible for adapting these suggested guidelines as appropriate for their work environment and in accordance with the latest guidance from applicable local and national public health authorities.

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