PSCI Virtual Auditor Training

November 24 – 25 and December 02 – 03, 2020 (India time)

Livestream platform – WTV

(details to be shared in confirmation email before the event)

Program Agenda

The goals of the auditor training are to improve the HSE, Labor and Human rights skills of auditors to address specific risk in the pharmaceutical sector; to ensure that all auditors meet the minimum qualifications and experience required to conduct PSCI audits; to improve the overall quality of the PSCI shared audits.

To promote transparency, this year for the first time we're also opening the registration to our suppliers, as we think this is an opportunity for them to learn more about PSCI audit requirements and common issues identified, so that suppliers could improve their performance accordingly.

Meeting outline:

Session	Date	Topics
Day 1	**24** November 2020 (Tuesday)	PSCI Audit Update; Labor and Human Rights
Day 2	**25** November 2020 (Wednesday)	Environmental Protection; PiE and AMR
Day 3	**02** December 2020 (Wednesday)	Process Safety; Emergency Preparedness & Response
Day 4	**03** December2020 (Thursday)	General Safety; Occupational Health and Industrial Hygiene; High Risk Work and Red Flags for Dangerous Working

Day 1 - Tuesday, November 24, 2020

PSCI Audit Update; Labor and Human Rights	
13:15 – 13:30	**Registration**
13:30 – 13:40	**PSCI Welcome and Opening Address (10 mins)** **Birgit Isabelle Skuballa**, Head HSE Audit & Supplier Management, Bayer **Maggie Zhang,** Partner Manager, Carnstone
13:40 – 14:55	**PSCI Audit Update 2020 (1hr)** The presentation will provide a comprehensive overview on the PSCI Audit program, including current updates regarding the PSCI self-assessment questionnaires and report templates, guidance tools for auditors as well as tip/hints for audit preparation (both for auditors and auditees) and conduct (onsite and remote).The presentation will also cover important post audit activities like audit report generation, including tips and support on how to write audit findings and to classify them. **Birgit Isabelle Skuballa**, Head HSE Audit & Supplier Management, Bayer *Q&A (15 mins)*
14:55 – 15:05	**BREAK (10 mins)**
15:10 – 16:25	**Corporate Responsibility with a Social Compliance Audits (1hr)** The presentation will give a brief overview of what social compliance audit is and the needs of social compliance audits. It will also illustrate the types, key procedures, and common issues of social compliance. Two case studies will be shared at the end of the presentation. **Dinesh Subhedar** Group Third Party Risk Management -Labour Rights (India and West Asia), Novartis (NBS Human Resources) *Q&A (15 mins)*
16:25 -16:45	**Exam (20 mins)**
16:45 – 17:00	**Closing Comments / end of day 1**

Day 2 - Wednesday, November 25, 2020

Environmental Protection; PiE and AMR	
13:15 – 13:30	**Registration**
13:30 – 14:45	**Environmental protection (40 mins)** A presentation about the growing environmental issues of pharmaceuticals in the environment and insights of audit findings. **Manjit Singh**, Associate Director- Corporate Sustainability, Centrient Pharmaceuticals **Stormwater management and Zero Liquid Discharge key points (20 mins)** Stormwater management best practice and key points to look out in zero liquid discharge ETPs. **Daniel Rehm,** HSE Advisor, External Manufacturing EMEA & API, Elanco *Q&A (15 mins)*
14:45 – 14:55	**BREAK (10 mins)**
15:00 – 16:15	**Introduction to PiE and AMR (30 mins)** An introduction to the issues of pharmaceuticals in the environment and the possible occurrence antimicrobial resistance caused by manufacturing discharges of antibiotics. There will also be an introduction to the AMR Industry Alliance's Common Antibiotic Manufacturing Framework and discharge limits that will help manufacturing sites control their antibiotic environmental emissions. **Dr Paul Barnett**, Director, Environment Health & Safety, GlaxoSmithKline **Assessing Antibiotic Manufacturing Sites Capability in Controlling their Antibiotic Emissions (30 mins)** An introduction to the methodology of conducting a mass balance to assess a manufacturing sites antibiotic wastewater discharges and what elements of the PSCI audit protocol are relevant to assessing compliance with the Common Antibiotic Manufacturing Framework **Jonathan Stanway**, Downstream & Pilot Plant Manager, Biotechnology & Environmental Shared Service, Pharma Supply Chain, GlaxoSmithKline *Q&A (15 mins)*
16:15 -16:35	**Exam (20 mins)**
16:35 – 16:45	**Closing Comments / end of day 2**

DAY 3 – Wednesday, December 02, 2020

Process Safety; Emergency Preparedness & Response	
13:15 – 13:30	**Registration**
13:30 – 14:45	**Process safety risk – Identifying reactive hazards and powder processing hazard in pharmaceutical industry (1hr)** The presentation will help audiences to understand reactive hazards and powder processing hazard in pharmaceutical industry. It will also review PSCI questionnaires and typical observations related to process safety. **Kumarkrishna Bhattacharjee**, Head HS&E Supplier Assurance and Risk India Region, Novartis *Q&A (15 mins)*
14:45 – 14:55	**BREAK (10 mins)**
15:00 – 16:15	**Emergency preparedness & response (1hr)** Presentation on emergency response, fire protection basics, hazard information and an introduction to sprinkler protection. **Daniel Rehm**, HSE Advisor, External Manufacturing EMEA & API, Elanco *Q&A (15 mins)*
16:15 -16:35	**Exam (20 mins)**
16:35 – 16:45	**Closing Comments / end of day 3**

DAY 4 – Thursday, December 03, 2020

General Safety; Occupational Health and Industrial Hygiene; High Risk Work and Red Flags for Dangerous Working	
13:15 – 13:30	**Registration**
13:30 – 14:15	**Plant General Safety (30 mins)** The presentation will discuss general plant safety topics such as personal protective equipment (PPE), safety training, chemical storage & handling, emergency response, accident/incident investigation, hazard communication (HAZCOM), process hazard analysis (PHA), safety equipment (fire extinguishers, water sprinklers), etc. It will focus more on six (6) life-critical safety topics – lock out tag out (LOTO), confined space entry (CSE), hot work (HW), machine guarding (MG), respiratory protection (RP), and fall protection (FP). **Pratap Padalkar**, Associate Director, Chemical Development & Manufacturing, Gilead *Q&A (15 mins)*
14:15 – 15:00	**Occupational health and industrial hygiene in plants (30 mins)** The presentation will discuss chemical exposure, noise exposure, radiation/bio safety, occupational exposure limits (OELs), safety data sheets (SDSs), respirator types, medical clearance, fit-testing, laboratory safety and engineering controls, emergency preparedness, etc. **Pratap Padalkar**, Associate Director, Chemical Development & Manufacturing, Gilead *Q&A (15 mins)*
15:00 -15:10	**BREAK (10 mins)**
15:15 – 16:15	**High risk work and red flags for dangerous working (45mins)** High risk work, including confined spaces, hot work, working at heights, lockout/tagout and electrical work accounts for the majority of serious workplace accidents and injuries (in some cases fatalities) at a site. In many cases, these incidents can be prevented. Therefore, the session will give an overview of areas to focus on during a site assessment and commonly observed gaps in these programs. **Roberta Haski,** HSE Leader, External Manufacturing & Commercial, Asia Pacific, Japan, ANZ *Q&A (15 mins)*
16:15 – 16:35	**Exam (20 mins)**
16:35 – 16:45	**Closing comments / end of day 4**