PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

2024 PSCI China Supplier Conference
PSCI 中国供应商大会（南京）

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BSI与抗生素耐药性认证

BSI Kitemark™ for minimized risk of antimicrobial resistance

于东 | 商务经理 | 英国标准协会
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嘉宾介绍 Speaker Bio

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- 公司：英国标准协会
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- 背景：2004年大学本科生物工程专业毕业，百威哈尔滨啤酒有限公司担任3年生产经理，2007年加入SK集团从事化工领域工作15年，熟悉食品与化工领域工作与管理流程
- 2023年加入BSI负责产品认证工作，帮助中国企业出海，同时负责AMR认证在中国的推广工作

议程 Agenda

英国标准协会（BSI）&抗生素耐药性认证介绍

英国标准协会(BSI）简介

AMR（抗生素耐药性）背景与标准历程

AMR认证的意义与驱动因素

AMR认证风筝标志的价值与收益

AMR认证的框架与流程

AMR认证目前进展与材料获取

BSI 百年里程碑(Centennial milestone)

1900

1901 在伦敦成立工程标准委员会

1903 风筝标志发布首个国家标准

1929 获英国皇家特许认可,成为世界首家国家级标准机构

1931 正式启用BSI英国标准协会的名称

1946 国际标准化组织(ISO)创始成员

1964 欧洲标准化组织创始成员

1995 BSI进入中国，协助中国培养了第一批专业审核员，并帮助中国建立认证制度

2002 收购KPMG毕马威北美管理体系认证业务，成为北美最大的认证机构之一

2003 2003-2020，连续十七年被国际公认品牌裁决机构选为全球性超级品牌

2012 将“追求卓越”作为百年品牌的文化结晶，启用全新标识Making Excellence a Habit

2021

联盟创始成员
原研和仿制药公司

AMR标准历程

联盟发展出生产框架，BSI将其转化为行业标准和认证

通用抗生素生产框架和PNEC
Common Antibiotic Manufacturing Framework & PNECs

- Member companies developed the Framework and made a commitment to implement along supply chain

从2018年开始一直到2021年持续报告实施进展

行业标准&BSI认证
Industry Standard & BSI Certification

- Created an industry standard and a certification scheme
- Moving from self-declaration to **3rd party verification** that PNECs are met

2022年发布标准，2023年Q2开始实施认证方案

标准和认证的广泛采用
Widespread Adoption of Standard and Certification

制造方(API/DP）考虑采用标准和认证

- **Manufacturers (API/DP)**: Consider standard and certification adoption

采购方考虑标书中具体指明

- **Procurers**: Consider specifying in tenders

2023年以后

AMR认证的意义

背景与驱动因素：制药行业供应商
Background and drivers –Pharma industry suppliers

背景

环境废弃物排放

多年来，全球一直试图通过AMR行业联盟、PSCI、PiE工作组等行业组织，以自愿方式来解决这一问题。

然而，强制控制废物排放，特别是抗生素排放的驱动因素现在越来越广泛。加强企业废物排放控制的驱动因素，如右侧

控制废物排放的驱动因素

#1：客户监督-尽管一些制造商评估了其生产对环境的影响，但含API成分的废物排放通常不受全球监管。在这种情况下，制造商通过其合同要求和供应商审核推动了这一要求。行业计划-PSCI要求关注环境废物排放和质量平衡计算。如果您已经进行了审核并符合PSCI SAQ的环境主题，那么您已经做好了准备。

#2：医疗系统招标：全球药品供应商——正面临医疗系统/医院的招标要求，以展示他们如何强有力的控制抗生素排放，不单他们自己，还必须证明废物排放从供应链端已经进行了强效控制

AMR认证的意义

背景与驱动因素：制药行业供应商
Background and drivers –Pharma industry suppliers

背景

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控制废物排放的驱动因素

#3：金融投资-投资界为生物制药行业制定了相关指导意见，要求公司披露关键的可持续性信息，包括环境、社会、公司治理（ESG）AMR是这其中关键支柱。

#4：国际AMR行动计划：在全球范围内，各国政府已经认识到本国没有可靠的抗生素来源对国家安全的威胁。通过这些国家战略，正在通过AMR将制造业和环境联系起来。

#5：联合国：联合国AMR高级别会议将于2024年9月举行，这是自2016年以来的首次

#6：未来监管：WHO指南草案：WHO关于药品生产中废物和废水管理的指南公众咨询期，重点是抗生素生产

驱动因素#1：客户的审计和监督——环境排放

除了PSCI客户审计和客户要求外，您如何积极遵守这些废水排放要求

根据PSCI的要求:重点关注环境中的AMR

Indicate which methods are used to manage process wastewater from this facility.

- Pretreatment of process water
  Please describe method(s) (example – hydrolysis with caustic or heat pre-treatment):
- ii. On-site wastewater treatment:
  Please describe:
  Does the facility collect, store, and analyze samples of:
  Wastewater?
  Sludge?
- iii. Discharge to an offsite treatment facility:
  Please describe off-site treatment method (example - biological treatment followed by activated carbon filter):
- iv. Discharge to a settling/retention pond:
  Please describe:
- v. Discharge to surface water (e.g., river, lake, ocean):
  Please describe:
- vi. Collection and transfer to an off-site wastewater management facility/company:
  Please describe:
- vii. Other, e.g. Zero liquid discharge, wastewater for irrigation, evaporation via cooling tower, incineration; deep well injection:
  Please describe:
- viii. Are risk assessments conducted and controls established to minimise discharge of APIs into the environment?.
- ix. Are API residues in wastewater quantified?
- x. Please describe method of quantification e.g. mass balance calculation, sampling with sufficiently sensitive methods etc.?
- i. Are API residues in the wastewater below the Predicted No Effect Concentration (PNEC) for those APIs (i.e. PEC/PNEC <1)?

AMR行业联盟：致供应商的信函，传达对标准和BSI认证实施的期望

What the AMRIA and its members expect of Antibiotic Suppliers

AMRIA believes uptake of the Standard through independent certification is an essential step in ensuring that antibiotic manufacturing does not increase the risk of AMR development. AMRIA and its members call on antibiotic suppliers to adopt the Antibiotic Manufacturing Standard and to consider seeking BSI certification to the standard. By doing so, suppliers will be able to transparently demonstrate to stakeholders, including customers, that they manufacture antibiot responsibly and are doing their part to mitigate risks associated with a global public health threat, helping to assure access to responsibly made antibiotics.

Restricted

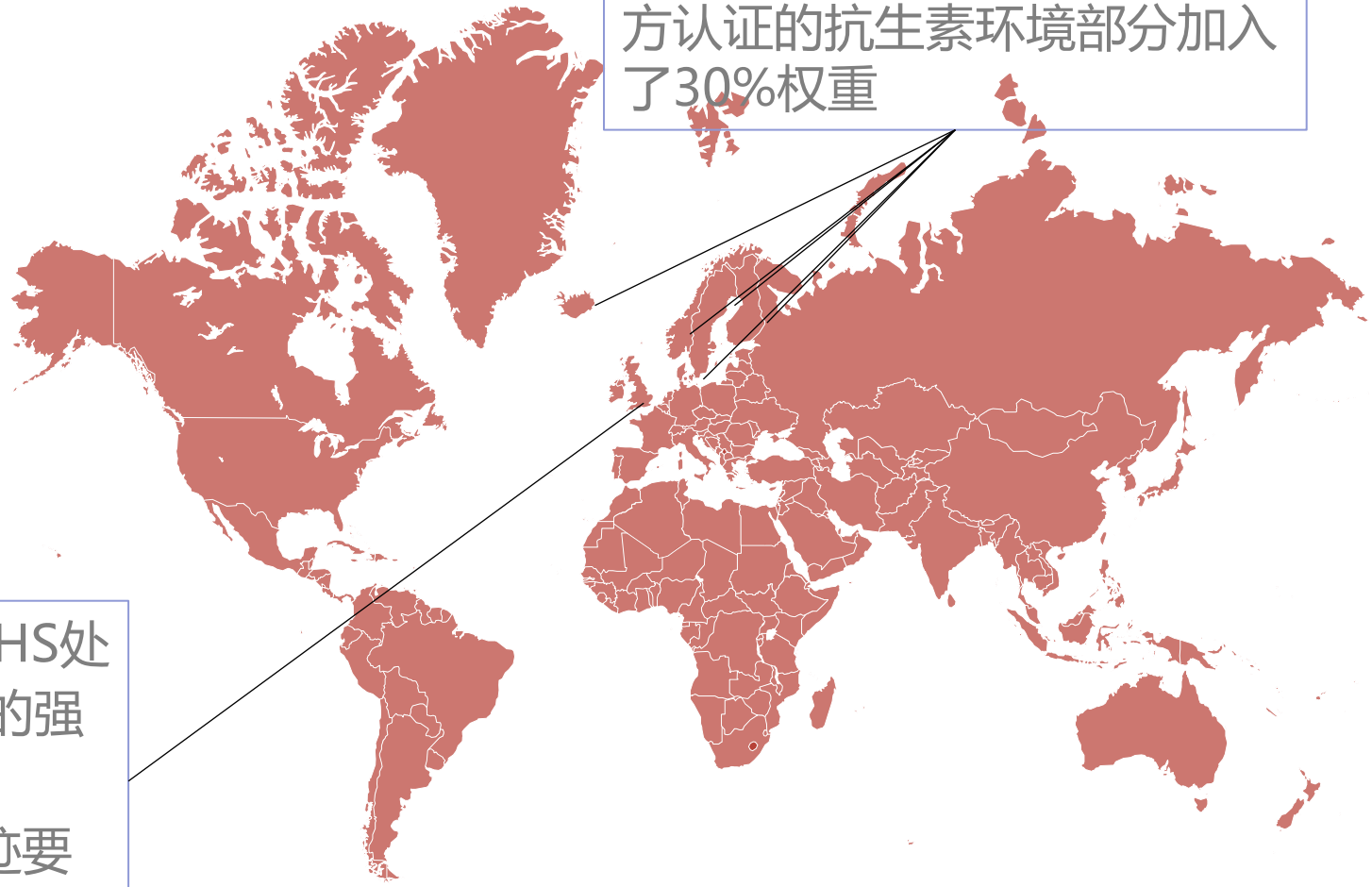
amr INDUSTRY ALLIANCE

Supplier Communication: Responsible Antibiotic Manufacturing

驱动因素#2：医疗系统招标引入AMR要求

随着医疗保健系统引入AMR的招标要求，将抗生素投放市场的组织及其供应链都需要证明其对生产中废物的有力控制

在北欧医学论坛的推动下，丹麦- – legacy antibiotics - 2023年招标，对于获得第三方认证的抗生素环境部分加入了30%权重



英国和爱尔兰-2023年7月NHS处方模版引入抗生素生产标准的强制性3RD评估
净零路线图-2028产品碳足迹要求

1. antimicrobial-products-subscription-model--guidance-on-commercial-arrangements--1.pdf (england.nhs.uk)

驱动因素#2：医疗保健系统抗生素招标标准——关注环境排放

您的客户----全球药品供应商——正面临医疗系统/医院的招标要求，以展示他们如何强有力的控制抗生素排放，不单他们自己，还必须证明废物排放从供应链端已经进行了强效控制

2023年12月北欧5国抗生素招标项目

Nr	Requirement	Information to provider
1	The product offered should be manufactured by a supplier that can demonstrate compliance to AMRIA Antibiotic Manufacturing Standard or similar manufacturing standard that combats antimicrobial resistance throughout the supply chain. To achieve the highest score, this must be certified by a third party or certification process has started.	Enter answer option. The purpose of the requirement is to achieve the least possible environmental impact in the manufacturing processes for the products and to avoid antibiotic resistance as a result of the production of the offered product. The supplier should provide evidence upon request of compliance to the standard. https://www.amrindustryalliance.org/shared-goals/common-antibiotic-manufacturing-framework/

	Answer option	Score	Justification
1	The supplier is compliant to AMRIA Antibiotic Manufacturing Standard or similar standard that combats antibiotic resistance throughout the whole supply chain, and this is certified by a 3. Party. (Specify which standard and 3rd party certification has been used, or will be used)	10	The supplier fulfills the requirement.
2	The supplier is compliant to AMRIA Antibiotic Manufacturing Standard or similar that combats antibiotic resistance throughout the whole supply chain, but this is not certified by a 3. Party.	8	The supplier fulfills the requirement to a large extent.
3	The supplier is compliant to AMRIA Antibiotic Manufacturing standard in parts of the supply chain (specify which part).	5	The supplier partially fulfills the requirement.
4	Does not follow the AMRIA Antibiotic Manufacturing standard.	0	The supplier does not fulfill the requirement.
5	Don't know.	0	The supplier does not fulfill the requirement.
6		0	The supplier does not fulfill the requirement.

供应商需符合AMRIA抗生素生产标准或在整个供应链中采用了控制抗生素耐药性的类似标准，并通过了第3方认证。(具体标准并已经进行第3方认证，或即将完成认证)

驱动因素#2：医疗保健系统抗生素招标标准——关注环境排放

您的客户----全球药品供应商——正面临医疗系统/医院的招标要求，以展示他们如何强有力的控制抗生素排放，不单他们自己，还必须证明废物排放从供应链端已经进行了强效控制

NHS England subscription model：

新型抗生素招标。英国国家医疗服务体系关于抗生素订购模式的咨询反馈已经在这里公布。参考了BSI标准/认证。这表明他们计划将认证作为强制性要求纳入最终招投标

Environmental standards

It was noted that the pilot model contract included the obligation to sign up to the AMR industry alliance on manufacturing standards.

Respondents raised the recent development of a BSI standard on manufacturing environmental standards and whether its inclusion in the model contract of the subscription model should be considered.

There was also a suggestion to include environmental standards in the eligibility criteria.

Environment

Many responses raised the environment standards as a contractual requirement, and requested clarity on what 'demonstrate compliance' would mean in practice.

One suggestion was to add "for example, by reference to BSI 'Minimized risk of antimicrobial resistance' certification to the [AMR Industry Alliance] standard 'minimizing risk of developing antimicrobial resistance and aquatic ecotoxicology in the environment from the manufacture of human antibiotics'."

驱动因素#3：金融投资者对制药行业的ESG引导

绿色债券取决于：制药公司具备强有力的可持续发展计划

作为ESG评估的关键支撑支柱，主要关注在供应链管理AMR环境影响

ESG报告中必须包括AMR进展的证据

驱动因素4： AMR国家行动计划

通过《抗生素耐药性国家行动计划》将环境与政策和行动联系起来

例如：英国发布了5年AMR国家行动计划，参考了行业标准和BSI认证

> UK 5-year action plan for antimicrobial resistance 2024 to 2029

Department for Environment Food & Rural Affairs

Department of Agriculture, Environment and Rural Affairs (Northern Ireland)

Department of Health (Northern Ireland)

Department of Health & Social Care

Scottish Government

Welsh Government

Policy paper

Confronting antimicrobial resistance 2024 to 2029

Updated 8 May 2024

Commitment 9.4 - Standards for manufacturing and waste management

We will collaborate internationally and with industry partners to promote the development and use of global standards and certification systems for environmentally responsible antimicrobial manufacturing in human and veterinary medicines.

Applies to the environment.

The manufacturing process for antimicrobials and their raw ingredients, whether for human or veterinary use, and the management of waste generated during production, are drivers of AMR. There is therefore a critical need for responsible production practices to prevent the release of antimicrobial residues into the environment, which can contribute to the development of drug-resistant pathogens.

This could include support of standards such as the antibiotic manufacturing standard developed by the AMR Industry Alliance and the British Standards Institute (BSI). This standard, published in 2022, can be used to assess the impact of pharmaceuticals in the environment.

Alongside this, the AMR Industry Alliance and BSI developed an industry certification program, which launched on 6 June 2023. The BSI will act as an independent and impartial assessment body that will enable antibiotic manufacturers to demonstrate that the requirements of the antibiotic manufacturing standard have been satisfied.

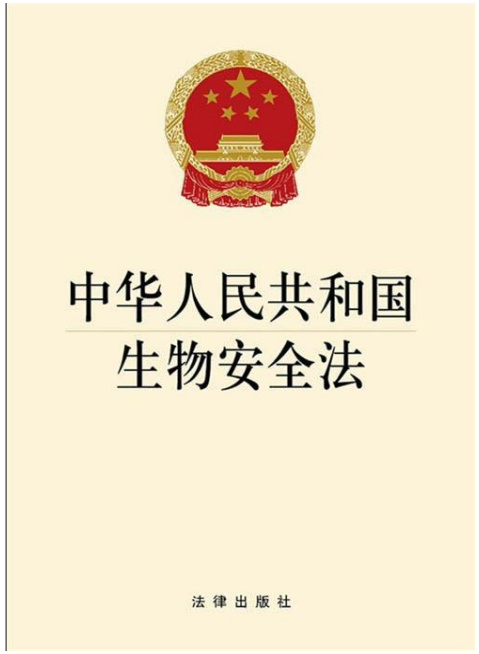
The aim of the standard and certification is to serve as a mechanism for antibiotic manufacturers to show evolving good practice. It gives industry the opportunity to demonstrate its ability to self-regulate independent of government regulation.

驱动因素4： AMR国家行动计划

2023年11月1日开始实施制药业工业污染防治技术指南，重点关注制药业API废物排放

今年第十四届全国人民代表大会常务委员会第九次会议审议通过最新《中华人民共和国生物安全法》将AMR列入重点管控对象

中国疾控中心周刊，将AMR列为主要专栏进行重点讨论

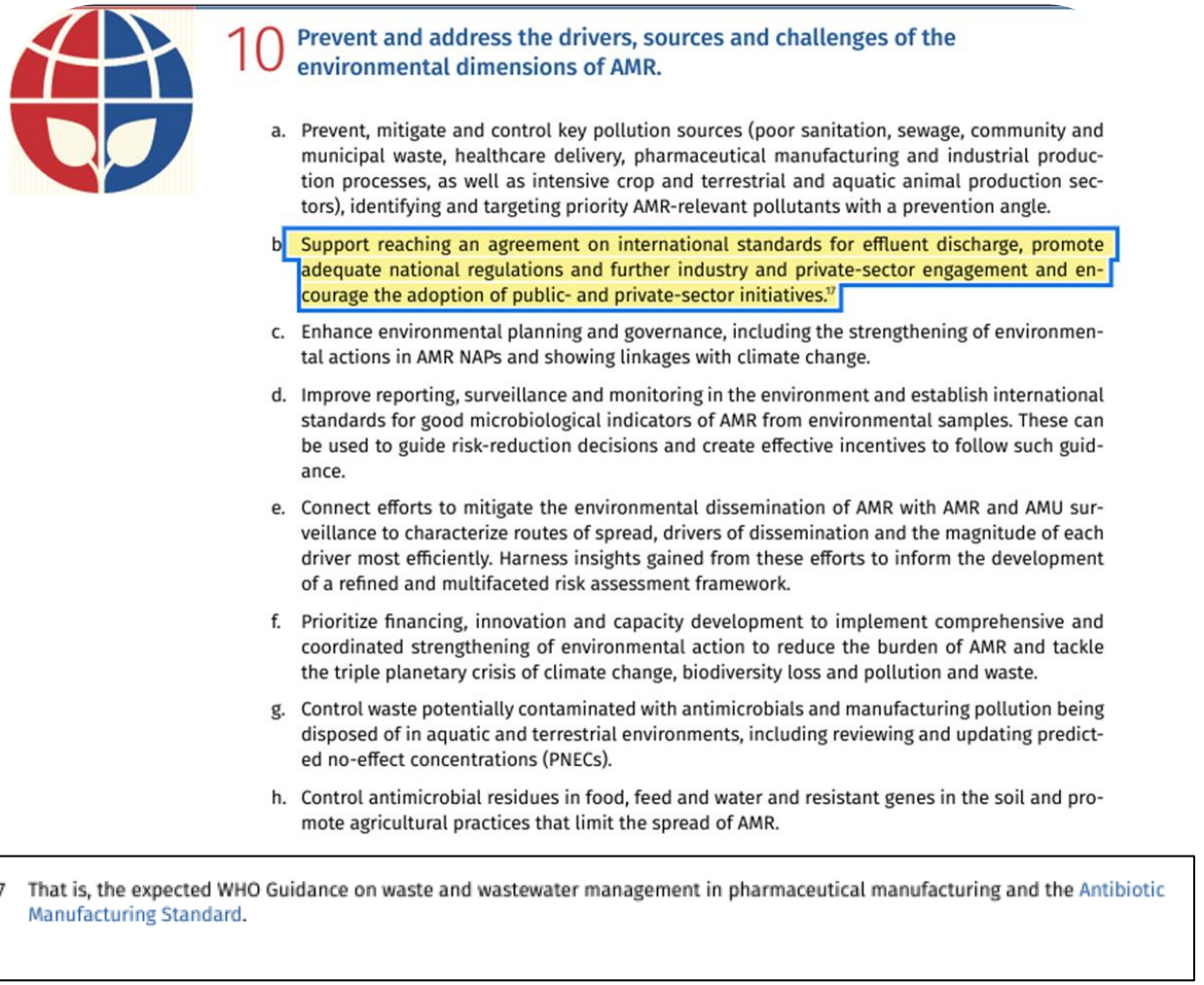


驱动因素#5：联合国关于抗生素耐药性高级别会议——关于优先事项的建议

2024年9月将举行自2016年以来的首次联合国抗生素耐药性高级别会议。

抗生素耐药性（AMR）多边伙伴关系平台在联合国高级别会议之前制定了一份建议清单，这是完整的文件，第10页，见右侧图片

BSI和AMR行业联盟的抗生素制造标准在9月份联合国AMR问题高级别会议中被正式提及



10 Prevent and address the drivers, sources and challenges of the environmental dimensions of AMR.

a. Prevent, mitigate and control key pollution sources (poor sanitation, sewage, community and municipal waste, healthcare delivery, pharmaceutical manufacturing and industrial production processes, as well as intensive crop and terrestrial and aquatic animal production sectors), identifying and targeting priority AMR-relevant pollutants with a prevention angle.

b. Support reaching an agreement on international standards for effluent discharge, promote adequate national regulations and further industry and private-sector engagement and encourage the adoption of public- and private-sector initiatives.[17]

c. Enhance environmental planning and governance, including the strengthening of environmental actions in AMR NAPs and showing linkages with climate change.

d. Improve reporting, surveillance and monitoring in the environment and establish international standards for good microbiological indicators of AMR from environmental samples. These can be used to guide risk-reduction decisions and create effective incentives to follow such guidance.

e. Connect efforts to mitigate the environmental dissemination of AMR with AMR and AMU surveillance to characterize routes of spread, drivers of dissemination and the magnitude of each driver most efficiently. Harness insights gained from these efforts to inform the development of a refined and multifaceted risk assessment framework.

f. Prioritize financing, innovation and capacity development to implement comprehensive and coordinated strengthening of environmental action to reduce the burden of AMR and tackle the triple planetary crisis of climate change, biodiversity loss and pollution and waste.

g. Control waste potentially contaminated with antimicrobials and manufacturing pollution being disposed of in aquatic and terrestrial environments, including reviewing and updating predicted no-effect concentrations (PNECs).

h. Control antimicrobial residues in food, feed and water and resistant genes in the soil and promote agricultural practices that limit the spread of AMR.

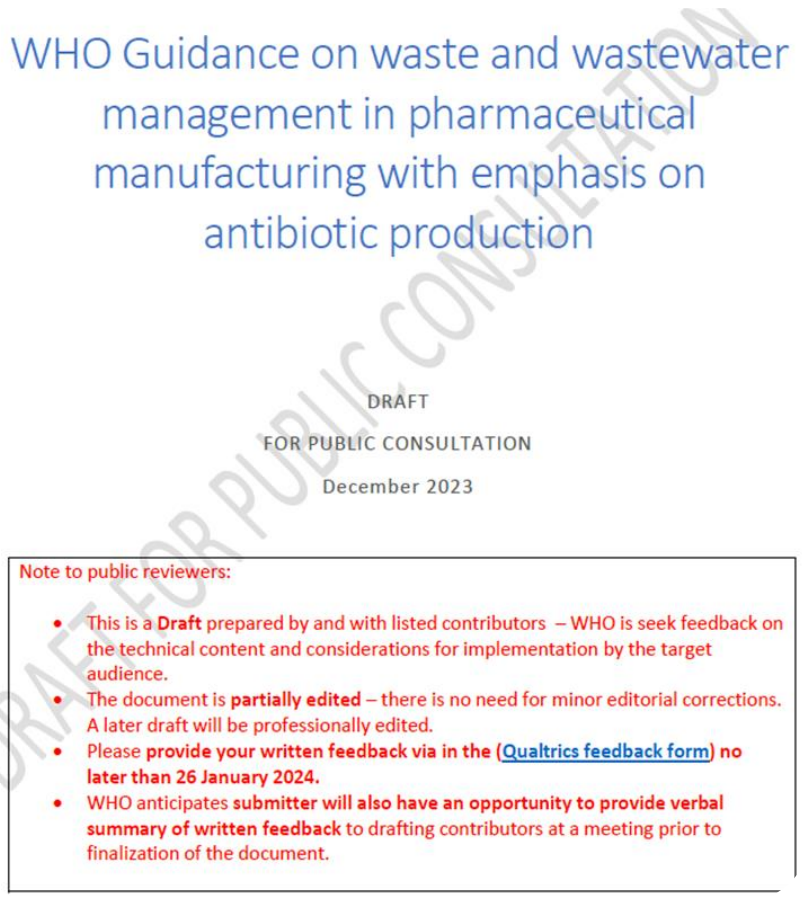
17 That is, the expected WHO Guidance on waste and wastewater management in pharmaceutical manufacturing and the Antibiotic Manufacturing Standard.

驱动因素6：未来监管——世卫组织指南

指导意见草案：世界卫生组织关于药品生产中废物和废水管理的指导意见，重点是抗生素生产。

指南正处于公众咨询阶段——初步迹象表明，BSI认证将在指南中引用。

该指南可用于指导全球各个药品监管机构（即EMA、FDA、MHRA）未来的监管政策


WHO Guidance on waste and wastewater management in pharmaceutical manufacturing with emphasis on antibiotic production

DRAFT

FOR PUBLIC CONSULTATION

December 2023

DRAFT FOR PUBLIC CONSULTATION

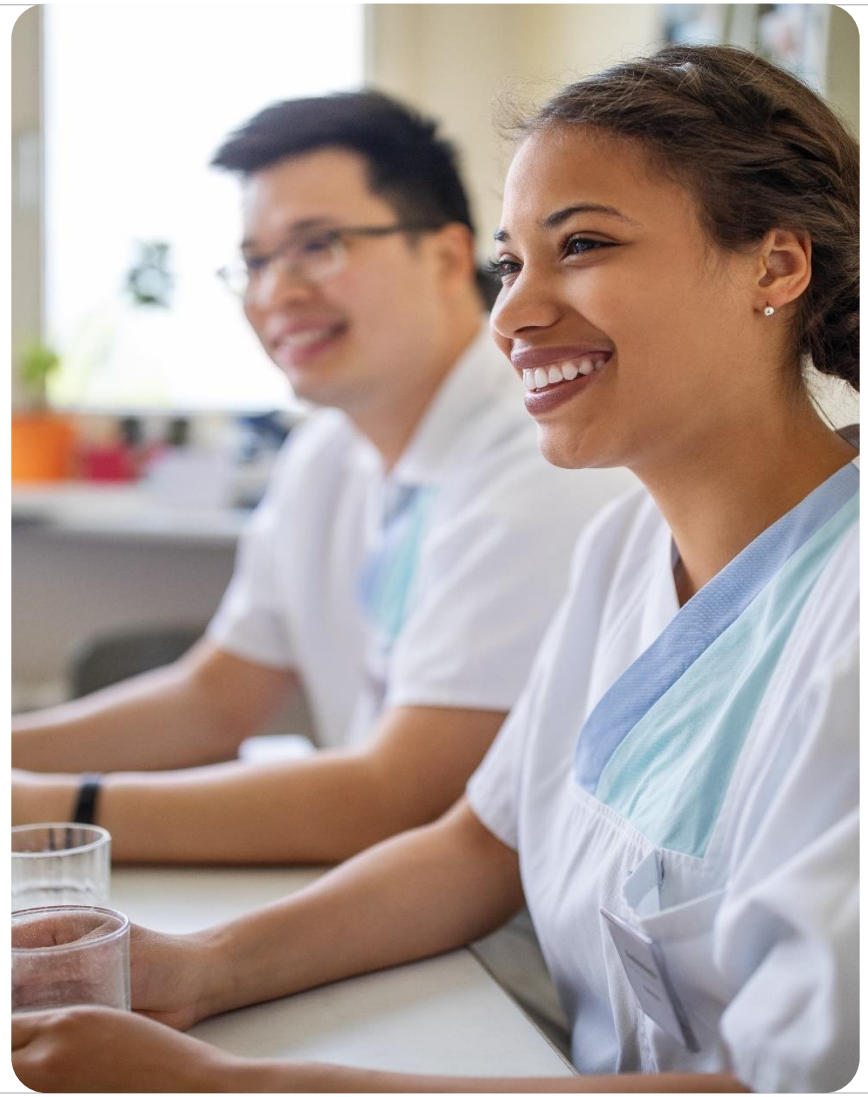
Note to public reviewers:

- This is a **Draft** prepared by and with listed contributors – WHO is seek feedback on the technical content and considerations for implementation by the target audience.
- The document is **partially edited** – there is no need for minor editorial corrections. A later draft will be professionally edited.
- Please **provide your written feedback via in the (Qualtrics feedback form) no later than 26 January 2024.**
- WHO anticipates **submitter will also have an opportunity to provide verbal summary of written feedback** to drafting contributors at a meeting prior to finalization of the document.

认证的收益

采购方以及利益相关方

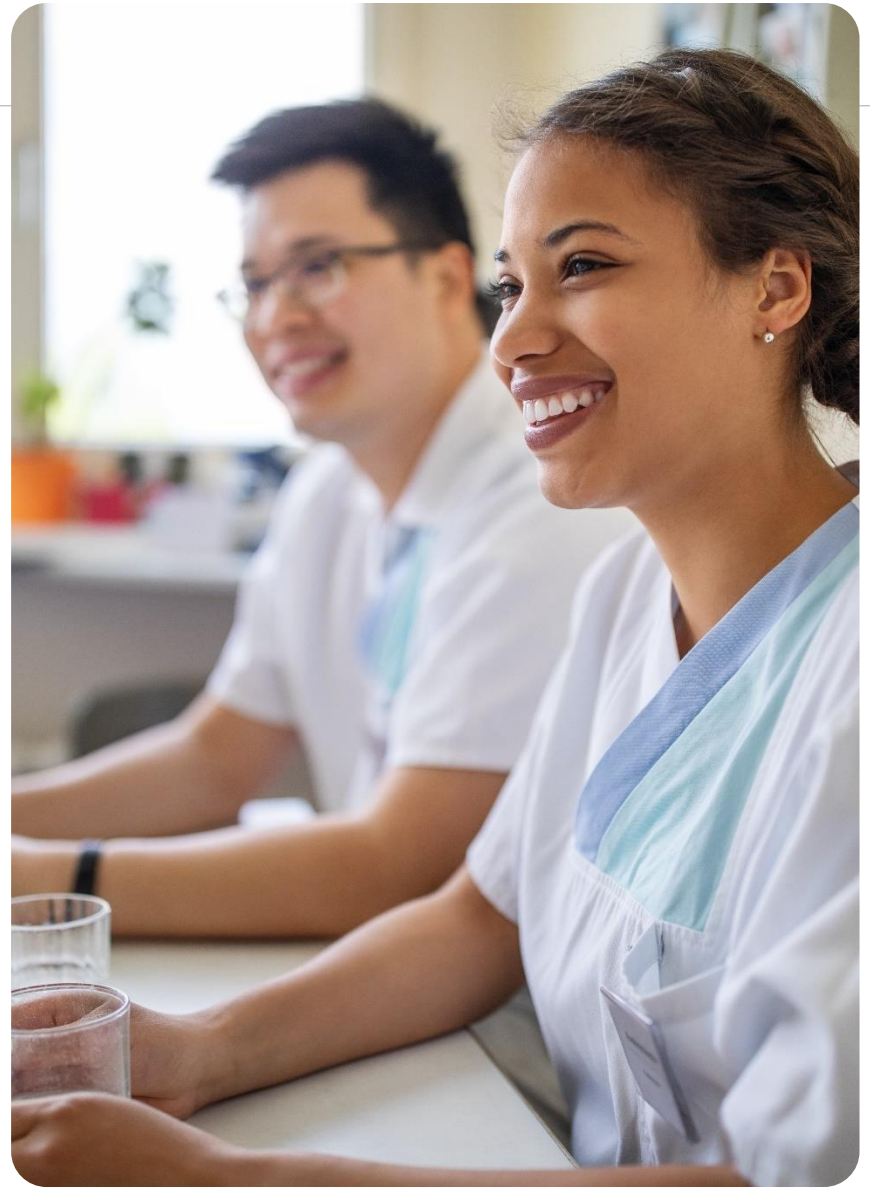
- 建立信任：独立的第三方认证，为全行业控制抗生素建立信任和信心
- 简化证据：通过基准验证，提供审核证书，证明您的做法是良好的，而不是无从对比的大量数据，简化了证据
- 供应链可见性：通过简单的证书链接，提升供应链的可见性
- 提高供应链的安全性：将API供应链有效监管，避免出现失控局面，实现可持续发展目标
- ESG层面：有效提升公司社会责任感，建立良好的公众形象



认证的收益

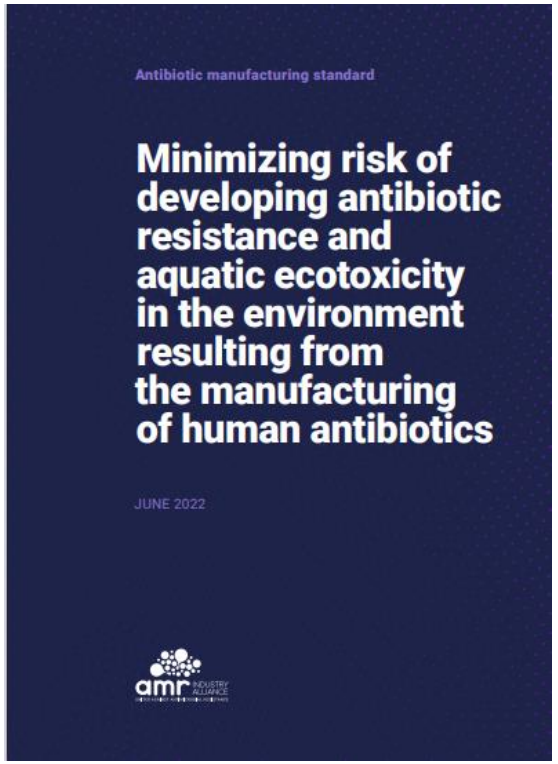
生产商

- 提升效率：通过认证，每个产品只需要一个评估，从而简化了流程。相比当前合规性评估方式（供应链和自有工厂）效率提高
- 差异化竞争：使你的产品脱颖而出，向客户证明您良好实践，并消除审核冗余
- 能力提升：利用AMR进行内部专业知识和能力建设、为科研提供信息并推进法规，与全球顶级制药公司保持同一水准
- ESG层面：独立认证，证明当前废物排放控制的有效性，支持采购和金融投资



Kitemark认证框架

关键因素：生产商需要通过化学工程计算（称为质量平衡）、采样和分析或零液体排放模型有效性证明，排放到环境中抗生素的预测或测量环境浓度PEC低于AMR行业联盟发布的PNEC（RQ<1）



+

Environmental management system ISO 14001:2015 – Clauses:
Planning Operations Performance valuation Continual Improvement

=

Certification decision

认证流程：通过强有力的认证获得信任

产品（API和/或最终药品）的生产过程评估

一阶段：远程 （中国现场）

程序文件审查

评估满足现场认证要求的能力

二阶段：现场

衡量程序的有效性

现场审核

验证质量平衡和/或取样分析或零液体排放（ZLD）方法，以验证是否符合PNEC

未被证明符合要求的地方将提出不符合项

- 次要要求在30天内提交原因分析和CAPA以供审查和验收
- 主要要求如上所述，并将包括额外评估以确认有效性
- 认证成功后，进入年度审核计划，以确保持续合规性能力
- 每3年进行一次重新认证

认证更新

BSI Kitemark™ for minimized risk of antimicrobial resistance

2024认证产品

Note: A product is an API or finished product at a unique site.

26个产品完成认证

Certified Products (API or Finished product)

2/3联盟成员

联盟成员正在积极沟通，最近已经向所有成员进行了介绍

54个产品正在进行

54个产品正在积极讨论去认证

11个待认证产品

4个国家预定了审核

8个国家设立网点

印度、西班牙、意大利、罗马尼亚、瑞士、奥地利、德国、瑞典

12个国家正在积极讨论设定网点

比利时、中国、法国、德国、印度、爱尔兰、意大利、挪威、波兰、葡萄牙、西班牙、美国

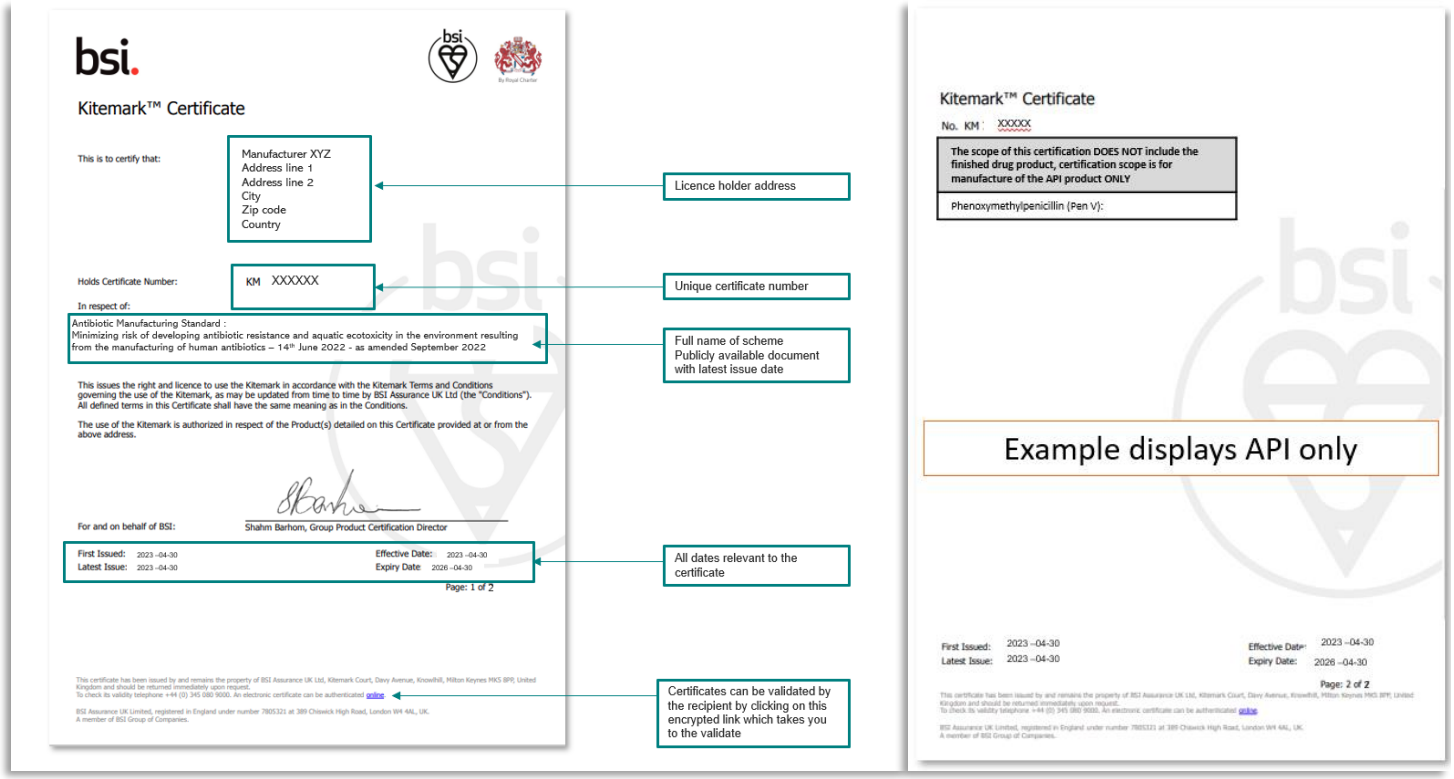
获得认证的产品

Purilex® Celfalexin	Amoxicillin / Clavulanic Acid	Puridrox® Cefadroxil	Sterile Ampicillin Sodium	Sterile Penicillin G Potassium	Azithromycin
Cotrim (Sulfamethoxazole Trimethoprim)	Sterile Penicillin G Procain	Sterile Amoxicillin Sodium	Ciprofloxacin Hydrochloride	Zavicefta Avibactam	Zavicefta Ceftazidime
Sterile Penicillin G Benzathin	Rocephin	Cotrim (Sulfamethoxazole Trimethoprim)	Phenoxymethylpenicillin (Pen V)	Sterile Penicillin G Sodium	Amoxicillin (enzymatic)

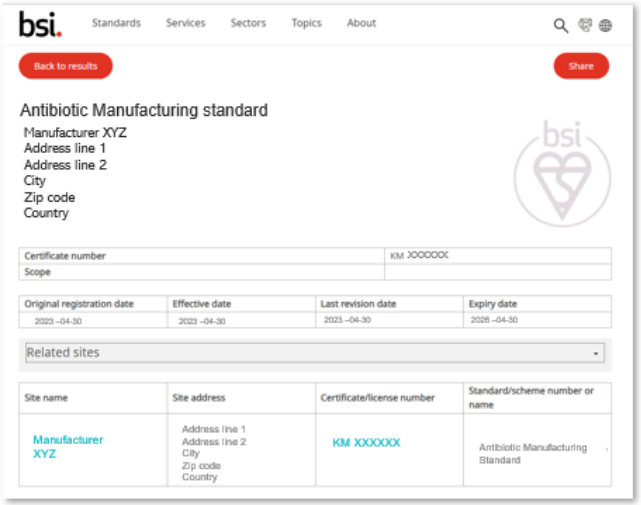
Phenoxymethyl-penicillin | Flucloxacillin | Pivmecillinam ←NEW

证书样式：增强供应链透明度

通过官方证书向利益相关者提供认证证据，证书可以在本地显示，也可以作为安全文档在线发送。



证书可以通过安全的全球验证网站进行独立验证



Validate via two secure routes;

A. **选择通过证书上的验证链接**
Selecting the live check validation link on the certificate

B. **通过BSI公开网站搜索证书编号或公司名称**
Searching for the certificate number or company name via the BSI publicly available website

撤回或暂停的证书将不可见
Certificates which are withdrawn or suspended will not be visible

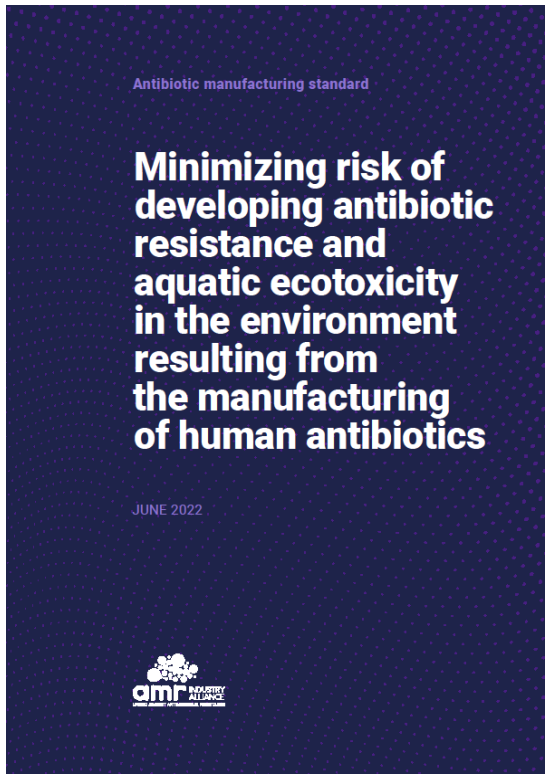
About AMR Kitemark Ceritfiction

Madaus GmbH (A Viatris Company) - Product Certification Kitemark	F. Hoffmann-La Roche AG - Minimized Risk of AMR Kitemark Certification
Viatris Pharmaceuticals LLC - Application: AMR Kitemark Certification	Mylan Laboratories Limited - AMR Certification Scheme - Pilot Program
Subtotal	Mylan Laboratories Limited - Minimized Risk of AMR Kitemark Certification
GSK PLC - Minimized Risk of Antimicrobial Resistance Kitemark	Novartis International AG - Minimized Risk of AMR Kitemark Certification (Certificate Issue
Subtotal	Novartis International - AMR Certification Scheme - Pilot Program
ACS DOBFAR SpA - AMR Kitemark Certification [Site: Tribiano]	PFIZER SERVICE COMPANY IRELAND UNLIMITED COMPANY - AMR Certification Scheme - P Program (Haupt Latina)
ACS DOBFAR SpA - AMR Kitemark Certification [Site: Verona]	PFIZER SERVICE COMPANY IRELAND UNLIMITED COMPANY - AMR Certification Scheme - P Program (Pfizer Ringaskiddy)
Alkem Laboratories - Product Certification Kitemark	Qilu Antibiotics Pharmaceutical Co.,LTD - Product Certification Kitemark
AMR Industry Alliance (Sponsor) - New Reg - Scheme Development - Phase 1	Recipharm Strängnäs AB - Minimized Risk of AMR Kitemark Certification
AMR Industry Alliance (Sponsor) - New Reg - Scheme Development - Phase 2 & 3	Sandoz GmbH - AMR Certification Scheme - Pilot Program
Antibióticos do Brasil Ltda. - Application: AMR Kitemark Certification	Sandoz GmbH - Minimized Risk of AMR Kitemark Certification
Centrient Pharmaceuticals Spain SA - AMR Certification Scheme - Pilot Program	TEVA GmbH - AMR Certification Scheme - Pilot Program
Centrient Pharmaceuticals Spain SA - Minimized Risk of AMR Kitemark Certification	TEVA GmbH - Minimized Risk of AMR Kitemark Certification
CIPLA LIMITED - AMR Kitemark Certification_MP	Viyash Life Sciences Pvt. Ltd. - Minimized Risk of AMR Kitemark Certification
F. Hoffmann-La Roche AG - AMR Certification Scheme - Pilot Program	

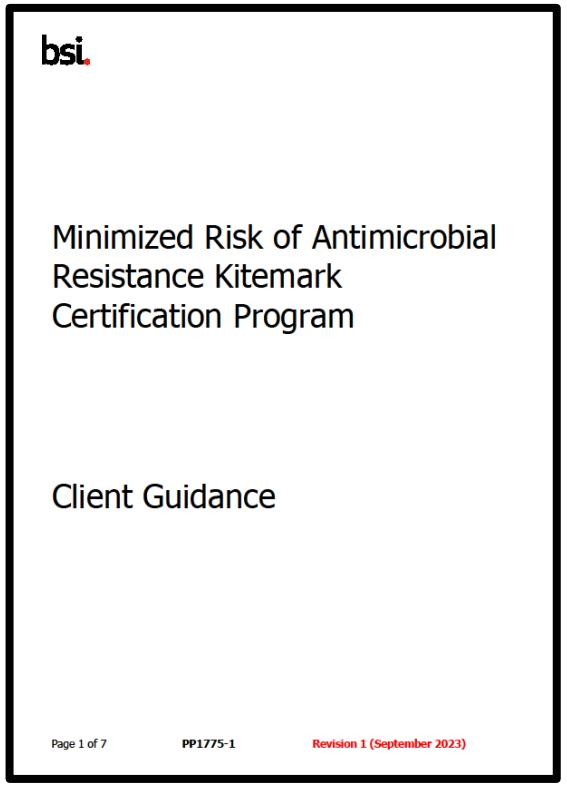
接下来您要做的

- 1-下载AMR行业联盟的抗生素生产标准-通读并确定是否准备好进行合规性认证
- 2-联系BSI提出您的申请，以便我们能够确定您的具体要求以获得认证
- 3-查看客户指南了解详细要求
- 4-通知相关股东您将获得认证

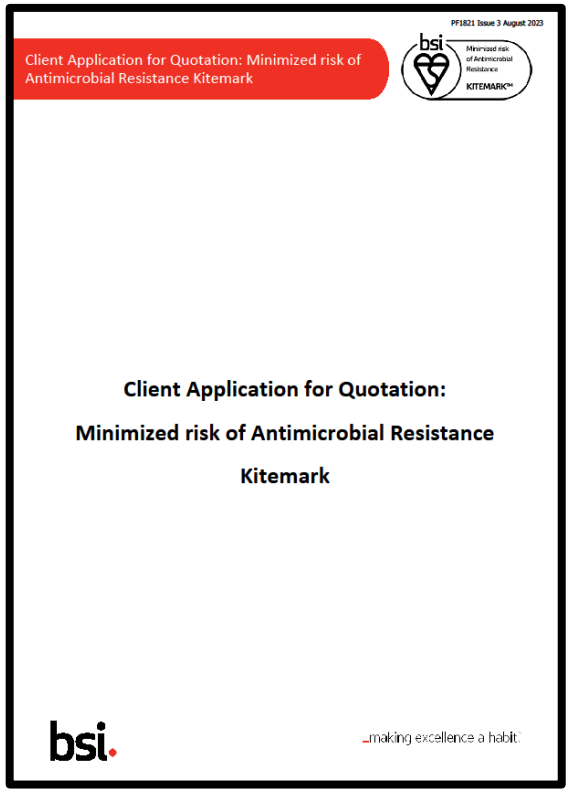
AMR认证材料获取



AMR标准手册
AMR Standard Book



客户指南
Client Guidance



范围申请表
Scoping form Application

Ongoing support and contact information

On behalf of the BSI team, I thank you for your attention and invite you to contact your

local representative for ongoing information and support of your AMR certification.

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建立信任、管理风险、拥抱机遇

感谢聆听

提问环节 Q&A