

AMR控制标准嘉宾圆桌

Panel: Antibiotic Manufacturing Standard

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嘉宾介绍

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- 于1995年加入辉瑞公司，担任辉瑞大连工厂EHS主管。于2009年加入辉瑞全球EHS组织，负责外部供应商EHS管理。
 - 获得大连理工大学化学工程学士和硕士学位。于2008年在沈阳药科大学完成硕士研究生课程学习



嘉宾介绍 Speaker Bio

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- 背景：

毕业于东南大学电气工程系电气技术专业，曾在国内半导体制造公司负责动力工程的运行和维护，1999年起在多家制药和医疗器械公司负责工厂HSE运行，2020年起负责供应商HSE管理。



内容提要 Content

- **AMRAI 是什么组织?** Who is AMRIA?
- **BSI 是什么组织?** Who is BSI?
- **是否了解这个标准和认证程序?** How to understand the standard and certification?
- **认证有哪些益处?** What are the benefits for manufacturers
- **认证有哪些要求?** What is required to achieve the certification
- **问答** Q&A

AMRIA 是什么组织? Who is AMRIA?

- **2017年建立** *"AMR Industry Alliance was established in 2017 as the life-science industry response to Antimicrobial Resistance"*
- **针对AMR提供可持续的解决方案** *"One of the largest private sector coalitions established to provide sustainable solutions to AMR"*
- **100多家成员公司** *"Bringing together 100+ biotech, diagnostics, generics & research-based pharmaceuticals companies"*
- **提供与利益相关方的合作机会** *"Enable collaboration opportunities with key stakeholders (e.g., WHO, CARB-X, GARDP, Wellcome Trust)"*



注：斜体字信息来源于AMRIA官方

AMRIA Alliance Manufacturing Members

R&D and generic biopharmaceutical companies



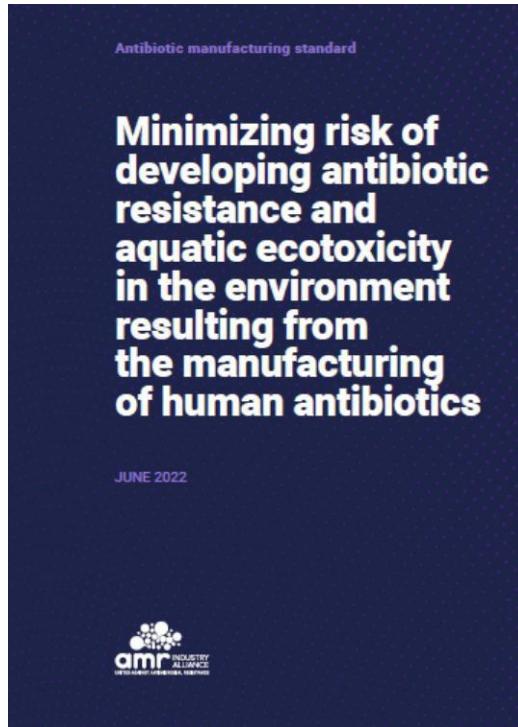
注：以上信息来源于AMRIA官方

BSI是什么组织? Who is BSI?



来源 Source: BSI

Antibiotic Manufacturing Standard - published June 2022



“Purpose of standard: To reduce the potential risk of development of antibiotic resistance (ABR) and risk of aquatic (surface water) ecotoxicity in the environment resulting from antibiotic manufacturing (API / Drug Product)”

来源 Source: AMRIA

[Link](#)

Certification scheme development

“This certification scheme development will comprise:

- *Creation of a certification scheme which encompasses the assessment against the Antibiotic Manufacturing Standard* 创建认证计划，包括根据抗生素生产标准进行评估
- *Creation of protocols which validate the reduction of impact from an antibiotic during the manufacturing process* 制定协议，验证抗生素在制造过程中的影响降低程度
- *Creation of guidance for applicants on the certification scheme requirements* 为申请人制定关于认证计划要求的指南
- *Provide assessment and certification decision criteria* 提供评估和认证决策标准
- *Implement a pilot process to test the certification process* 实施试点流程以测试认证流程”

斜体字内容来源 Source: BSI

What Are the Benefits to Manufacturers?

- **Differentiate your products to your customers** by demonstrating compliance to industry created best practice standard 通过证明遵守业界创建的最佳做法标准,让您的产品在客户面前与众不同
- **Assure internal stakeholders and leadership** of the effectiveness of the control of waste streams for your operations in relation to minimizing risk of AMR 式内部利益相关者和领导者确信在生产过程中对降低AMR风险相关的废物流控制措施有效
- **Reduce the need for duplicate supply chain audits on AMR** from your customers 减少客户对AMR的重复供应链审核需求
- **Drive continual improvement in your business practices** to align internal sites on waste control practices, to minimize the impact of AMR 推动业务实践不断改进,使内部工厂在废物控制方面保持一致,以最大程度降低AMR的影响

What is required to achieve the Kitemark?

To achieve this Kitemark, BSI will assess manufacturers to ensure they have为了获得BSI的认证，BSI将评估工厂以确保他们已经:

- Implemented the AMR Industry Alliance standard
执行了ARMIA 的标准
- Implemented select parts of ISO 14001
执行了ISO14001的部分标准
- A consistent method to calculate their PEC
有统一的方法计算PEC 值

问答Q&A

