Your partner in progress

Client Application Form:

Minimized risk of Antimicrobial Resistance Kitemark

BSI have launched the global Minimized risk of Antimicrobial resistance (AMR) Kitemark; designed to promote and attest to the responsible manufacturing of antibiotics in the global supply chain, helping to minimize the risk of aquatic toxicity in the environment and the spread of AMR.

Certification to the antibiotic manufacturing standard will be a clear sign that manufacturers in the global antibiotic supply chain are taking necessary steps to ensure antibiotics are made responsibly, helping to minimize the risk of releasing antibiotic waste emissions into the environment.

Based on the AMR industry Alliance standard, published in June 2022 and enhanced utilizing relevant elements of ISO 14001:2015. The Antibiotic Manufacturing Standard was facilitated by BSI for the AMR Industry Alliance, an organization made up of over 100 companies and associations from across the life-sciences industry with the shared goal of providing sustainable solutions to curb AMR.

The new certification, developed by BSI to support the Standard, offers independent third-party verification that waste streams containing antibiotic active pharmaceutical ingredient (API) and drug products are appropriately controlled during manufacturing by pharmaceutical companies. This certification program will involve initial evaluation against the requirements of the standard and annual surveillance to verify ongoing maintenance of the appropriate controls over time.

How does it work?

Certification is achieved by an Organization for a specific API and/or Drug product manufactured at an individual location. Upon application, BSI will initiate an assessment plan, beginning with an initial remote document review, followed by an on-site audit, to verify compliance with the requirements of the Minimized Risk of Antimicrobial Resistance Kitemark.

Products and locations that meet these requirements will be eligible for Certification. Certification of the antibiotic product is based on the findings of the Audit and the validation of the

data which determines the predicted environmental concentration (PEC) shall be less than the concentration believed to result in increased selection pressure on bacteria in the environment, known as the predicted no-effect concentration (PNEC). Where necessary the user shall apply controls or treatment to achieve the PNEC, where; PEC/PNEC = Risk quotient (RQ).

For full scheme requirements please refer to our Client Guidance document

Upon completion of the application, please email this form and any supporting documentation to: productcertification.sales@bsigroup.com

Minimized risk of Antimicrobial Resistance Kitemark – Process

Implement standards

AMR Industry Standard B477 2014+A1 2020
ISO 14001 2015
(select clauses)

Gap assessment

Optional stage to prepare for formal assessment

Assessment (stage 1)

Assess policies, procedures for intent to meet the requirements

Assessment (stage 2)

Assess effectiveness of implementation and validate the PEC calculation

Kitemark certificate issued

Maintained through regular assessment

Environmental management system ISO 14001:2015

- Planning
- Operations
- Performance valuation
- Continual improvement

Invoice

Invoice for application fee upon signing contract

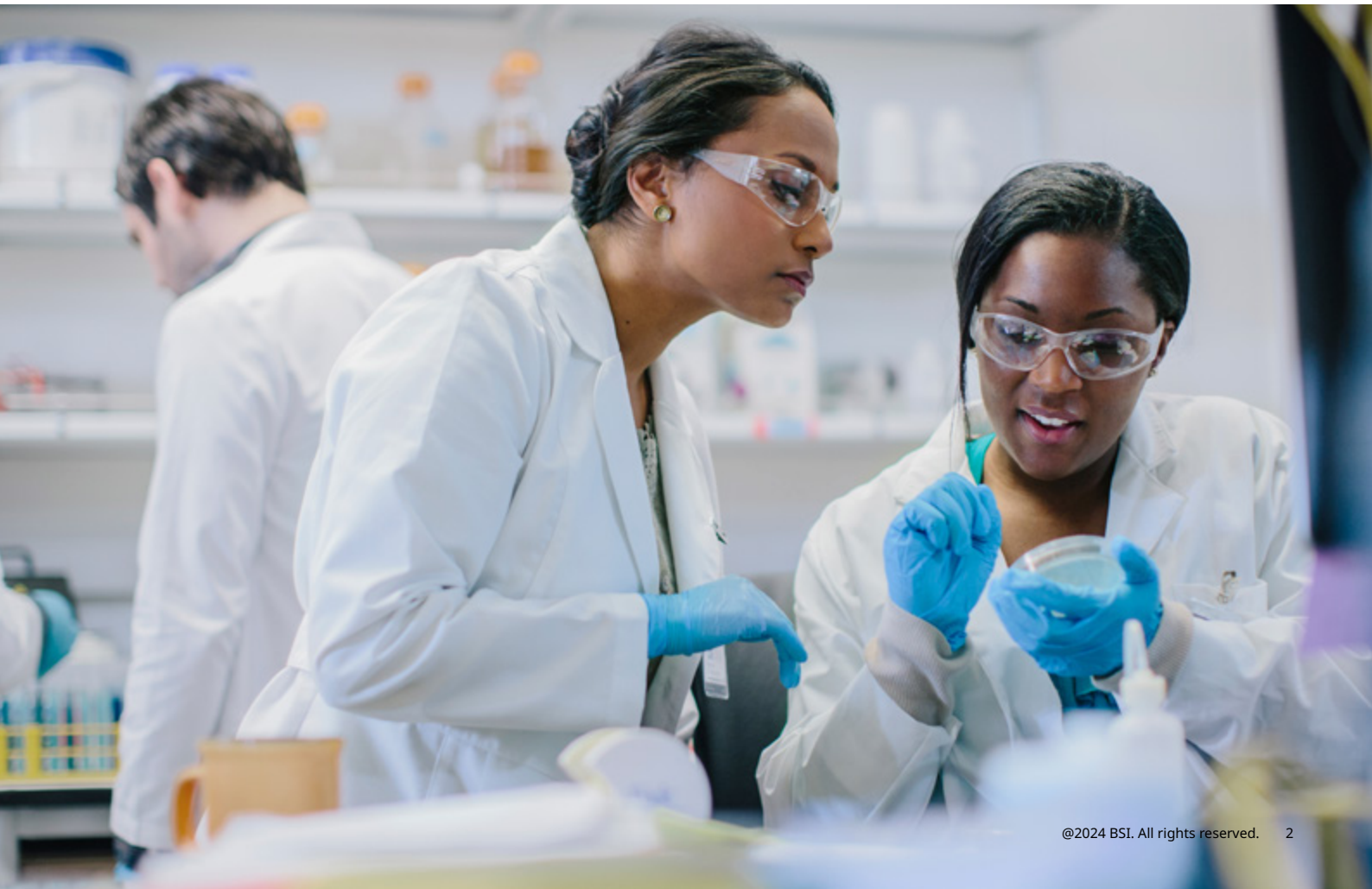
Audit report

Received an audit report and invoice after each assessment

Invoice

Action plan

Based on audit findings you will complete and submit an action plan for review and acceptance



Guidance for completing the BSI Kitemark for Minimized Risk of AMR certification application form

Section 1 – Client details

- **Applicant:** Provide the name and address to appear on the certificate. Note that the assessment site doesn't have to match the applicant's name.

- **Certification by product to individual site:**
  - If the client has multiple sites, a separate application form is required for each site.
  - If the client has multiple antibiotic products at a single site, they can be included in a single application form.

- **Manufacturer's details:** Specify the location of the manufacturing site where the assessment will take place.

Section 2 – Antibiotic product profile

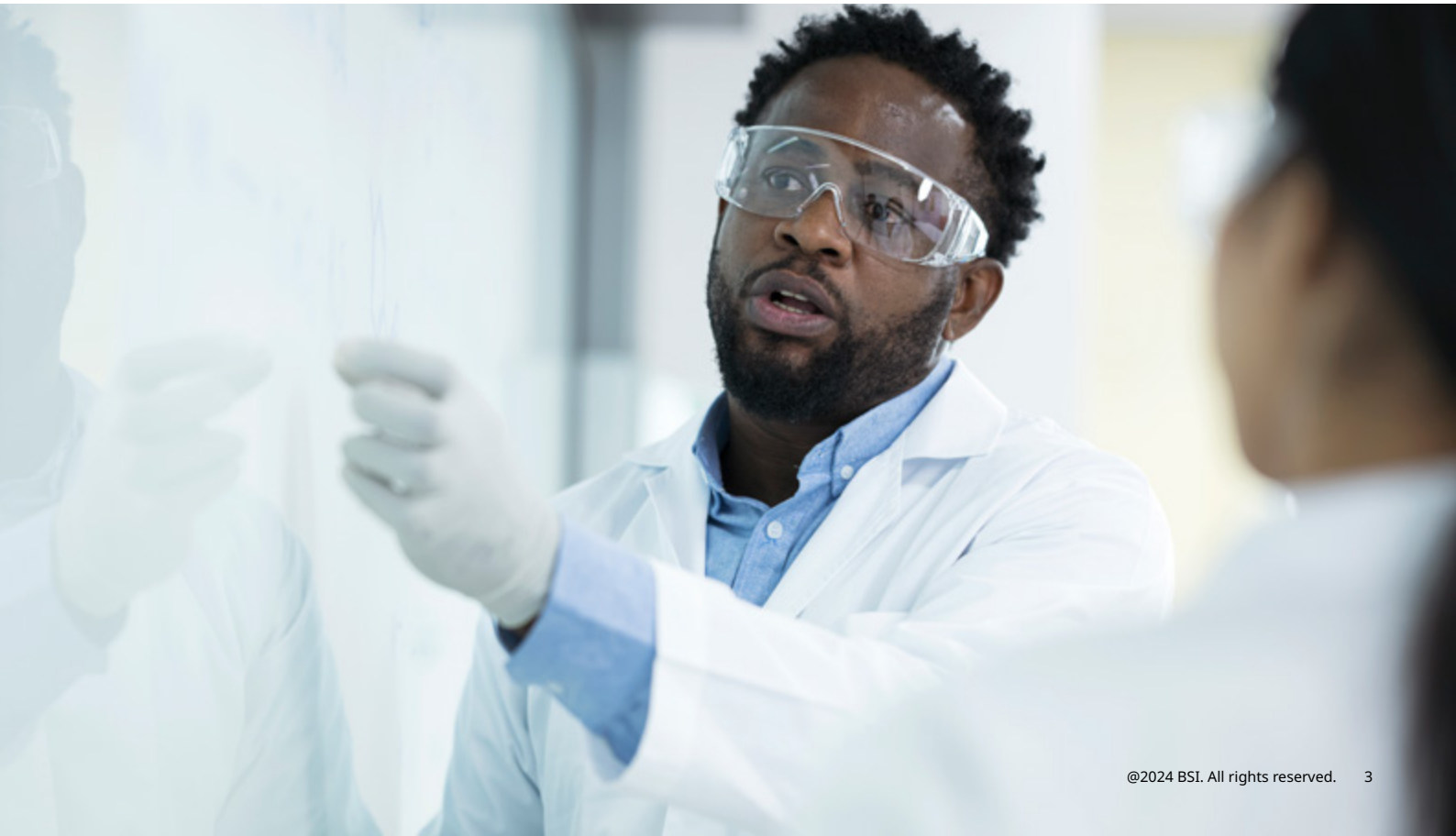
- **Batches vs. campaigns:** Multiple batches of the same product are often run sequentially in "campaigns" to minimize setup and quality costs. Understanding the number of batches helps define the duration of audits and identify opportunities for waste, losses, or discharge.
  - **Number of batches:** Provide an estimate of how many batches of the product are produced in a single campaign.
  - **Number of campaigns:** Indicate how often the product is produced, which helps determine if production is continuous or occurs a certain number of times per year.

Section 3 – Operational profile

- **Facility travel time:** Determine if travel time is required between facilities on a single site or if any travel to off-site facilities is necessary. Key related sites include:
  - Wastewater treatment
  - Warehousing/storage of waste
  - Primary packaging

- **Process flow diagram:** Provide a comprehensive process flow diagram to help understand the manufacturing steps required to produce the antibiotic. This assists the assessor in preparation and duration calculation, focusing on where wastewater and losses can occur.

- **PEC calculation:** State the method used to calculate the predicted environmental concentration (PEC).



Section 1 – Client details

Applicant details

Registered Company (legal entity) Name: .....

Address (to appear on certificate): .....

.....

Phone number: .....

Website: .....

Company registration number: .....

VAT number (where applicable): .....

Company trading name (if different than above): .....

Applicant contact details

Primary contact:

Name: .....

Title: .....

Phone: .....

Email: .....

Secondary contact:

Name: .....

Title: .....

Phone: .....

Email: .....

Details of agent/consultant that you authorize to act on your behalf (if applicable):

Contact: ..... Phone: .....

Email: .....

Invoice details (if different from above)

Company Name: ..... Contact: .....

Address: .....

Phone: ..... Email: .....

Company Registration Number: ..... VAT Number: .....

Manufacturer's details (if different from above) [site to be assessed]

Company Name: ..... Contact: .....

Address: .....

Phone: ..... Email: .....

Section 2 – Antibiotic product profile

	Product 1	Product 2	Product 3
Product Name*			
API or Drug Product?			
Types of Formulations and Concentrations			
Number of Batches (est. per annum)			
Number of Campaigns (est. per annum)			

*If applying for additional Products please provide details separately.

Section 3 – Operational profile

Site Information

Facility Size (ft2 or m2): .....

Please explain site location/campus (lot size; number of buildings) involved in production.

Where is the wastewater treatment facility (WWTF)? ◯ On-site ◯ Off-site ◯ Both

Please describe the wastewater treatment facilities involved in production.

- If on-site, please describe the type of treatment provided by the WWTF.
  (If tertiary treatment is used, please explain)
- If off-site, please provide details on location, ownership, operation and size of the treatment plant
- Please detail the type of treatment provided and receiving body where WWTF discharges.

Please explain any other off-site operations and the proximity/location of these processes:
Examples: warehousing (waste storage), primary packaging.

If off-site activities require assessment at other locations, please explain any site access or permission requirements that may exist:

Operational profile

Operational Information

Please provide below (or separately) a Process Flow Diagram for each product:
Be sure to highlight key processes in the Process Flow Diagram:

Manufacturing Steps

Step	Number of Steps involved
Cleaning	
Distilling	
Crystalizing	
Filtering	
Fermentation	
Evaporation	

Post manufacturing steps that include the processing of any byproduct (mother liquors) or sludges that include API, into auxiliary products.

Any off-site activities (off-site waste storage by site or site's warehouse contractor & off-site primary packaging).

How many steps within this process generate wastewater (including cleaning)? .....

Please confirm the method used to develop the PEC Calculation for this site.

☐ Mass Balance ☐ Sampling/Analysis

Audit Delivery

Date of earliest availability for Audit: .

Do you anticipate being in production (of Certified Product) during the initial Audit? ☐ Yes ☐ No

Are required documents available in English? ☐ Yes ☐ No

Will an interpreter be needed during assessments (non-English sites)? ☐ Yes ☐ No

Signatory & Date

Signature: ..... Date: .....

Name: ..... Position: .....

Thank you very much for your cooperation in completing this application! Please return it, along with any further diagrams, to productcertification.sales@bsigroup.com

