



# Sustainable Medicines Manufacturing Innovation Programme

**Developing new sustainability standards in  
medicines manufacturing**

Chris Nash

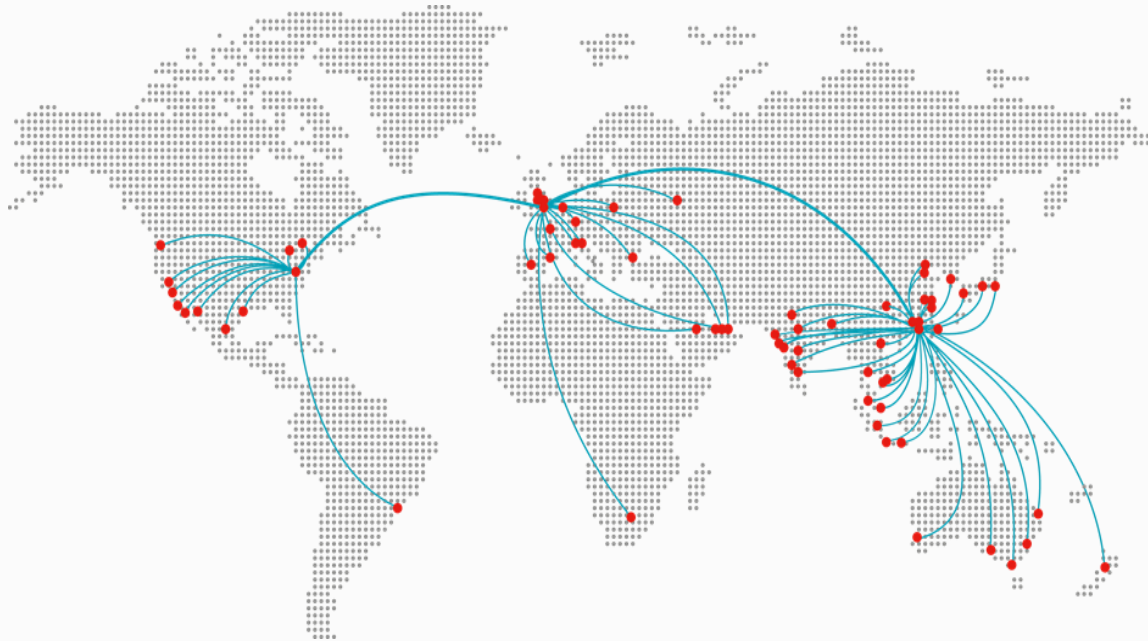
Courtney Soulsby

04/03/2025



# BSI – Accelerating progress towards a fair society and a sustainable world

## 84,000 clients in 93 countries...



We were responsible for originating many of the world's most used management standards and publish around 3,000 standards annually.



Established in 1901, BSI was the world's first National Standards Body and operate as a non-profit distributing organisation incorporated under Royal Charter



By Royal Charter

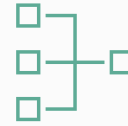


BSI is the UK's national member of international standards bodies, providing a platform to influence ISO, IEC, and EN standards.



# What are Standards?

- Standards are an agreed way of doing something
- Standards could relate to making a product, managing a process or delivering a service
- Standards are open, consensus-based documents, developed by thought-leaders who share an interest in improving how things are done
- Standards represent the distilled wisdom of what 'good' looks like, helping to make things work properly, and improve the way organisations do things



## Rigorous governance and consensus building

BSI are experts in developing methodological rigour through applying robust governance and processes to develop consensus-based materials



## Cross sector networks and international context

We have hundreds of committees and work across all sectors with knowledge and broad networks globally. We operate in 160+ countries and have delivered consulting projects internationally, with ability to influence large IGOs



## Impartiality

As a royal charter and non-profit distributing company, we have a strict governance for neutrality; we are not susceptible to industry influence, and always promote drive fairness and inclusivity across all our work

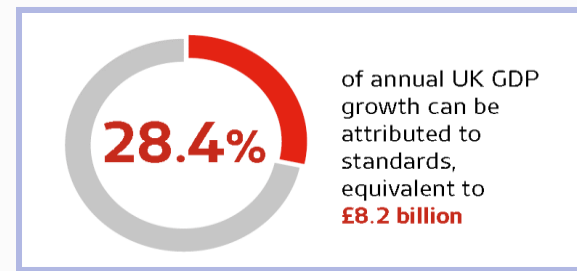
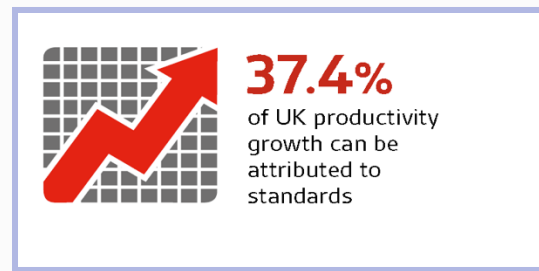


## Formalisation journey and link with the ISO system

As a national standards body we operate as part of a wider quality infrastructure system under ISO; we have the ability to influence, can formulate convergence and support the journey to formal standards

# The Value of Standards to the UK Economy

By setting clear benchmarks for safety, quality, and interoperability, standards support businesses in reducing costs, increasing efficiency, and accessing new markets.



In an increasingly complex and competitive global economy, standards are essential to ensure long-term resilience and innovation.

They provide a common framework that enables businesses to scale efficiently, adopt new technologies with confidence, and navigate regulatory landscapes.



*The Economic Contribution of Standards to the UK Economy*

– Centre for Economics and Business Research

# What can BSI provide?

## Standards Partner



*“Voluntary standards that describe agreed good practice can be a great enabler of innovation, playing a critical role in bridging the gap between brilliant ideas and commercial success.”*

Lord Callanan, Minister for Business, Energy and Corporate Responsibility – from [Standards for the Fourth Industrial Revolution](#)

# Partnering with Innovate UK to support innovators



- BSI has a long-term, strategic, relationship with Innovate UK underpinned by an overarching Framework Agreement
- The Framework covers our role, as the UK's National Standards Body, in leading standardization activities - from consensus building and industry engagement to standards creation, and sharing and enabling the use of best practice
- We help innovators bring new products to market, the scaling of innovation and UK leadership
- We also work with the wider UKRI ecosystem, including the Catapults network



# What are we doing with Innovate UK today?

We're leading strategic programmes, with Innovate UK, enabling safe, sustainable innovation, scaling and growth in areas as diverse as AI, transport and critical materials. For example:



## BridgeAI

As a strategic programme partner, we provide standards support to SMEs across key sectors to accelerate development and adoption of AI.



## Business Growth Toolkit

Providing access to over 111,000 standards for SMEs, inc. live online training on the benefit of participation in standards and the opportunity to comment on draft standards at public consultation



## Future Flight

We're leading a UKRI-funded programme to enable safe trials, demonstrations and industrialization of new classes of air vehicles through standards.



# Sustainable Medicines Projects





# UK Industrial Growth Strategy

## Security of supply

### Economic security and resilience

Geopolitical shifts, COVID-19, and Russia's invasion of Ukraine have exposed vulnerabilities and dependencies within the global trading environment.

Tackling these challenges and building a strong economy are complementary objectives – the UK's long-term growth needs to be secure and resilient, including by building a secure supply of critical goods. Building on the UK's existing strengths in areas such as **life sciences**, renewables and emerging technologies – for example AI – the UK can grow the economy and project strategic leadership at the forefront of geopolitical competition, while being better placed to respond to future shocks.

Our economic security objectives for the industrial strategy will be to:

- promote key sectors in the economy which drive growth and strengthen economic security
- reduce supply chain and other vulnerabilities in growth-driving sectors which could harm their long-term growth or ability to deliver critical outputs
- ensure national security risks inform the approach to driving growth in these sectors

Our industrial strategy, including our partnership with the Industrial Strategy Council, will help us think strategically about how we prioritise in support of these objectives.

Decisions that government and business make in the short- and long-term considerations to deliver growth that is resilient.

## Net Zero

### Net zero

The UK is committed to sustainable growth – growth that is aligned with our net zero and environmental objectives.

The UK approach will demonstrate global climate leadership, including focusing on supporting the clean energy mission. It will build a strong domestic industrial base across services and manufacturing to gain strategic economic advantage – creating good, well-paid jobs in the green sectors of today and of the future. This includes opportunities presented by the circular economy.

The net zero objectives for the industrial strategy will be to:

- capture the growth opportunities of the clean energy mission and net zero transition
- identify and support clean energy industrial sectors with the greatest growth potential.
- align sector plans with net zero and environmental objectives

## Innovative Manufacturing processes

### Life sciences

Over the next decade, the life sciences sector holds enormous potential to drive economic growth and productivity while significantly improving health outcomes for thousands of patients across the country. This sector delivers goods that are critical to the functioning of our economy and society and increases the UK's resilience, for example, to epidemics. Recent breakthroughs, such as the development of promising new vaccines targeting cancer, underscore the transformative impact of the sector. The UK's life sciences sector offers unparalleled opportunities for future economic growth, propelled by:

- new discoveries
- data availability
- AI
- groundbreaking treatments
- personalised healthcare
- **innovative manufacturing processes**

Crucially, the UK's life sciences sector is built on a strong foundation, with over 6,800 businesses in 2021 to 2022 that generated over £100 billion in turnover [\[footnote 88\]](#). The UK is also home to 4 of the top 10 global universities for life sciences and medicine, and with the expertise of the NHS, the UK is a global hub for innovation [\[footnote 89\]](#).

There is an opportunity to renew the UK's leadership in life sciences, strengthening and supporting the areas where the UK is already effective alongside bold innovation and collective partnership, with business, academia, and the health system to drive economic growth and build an NHS fit for the future.

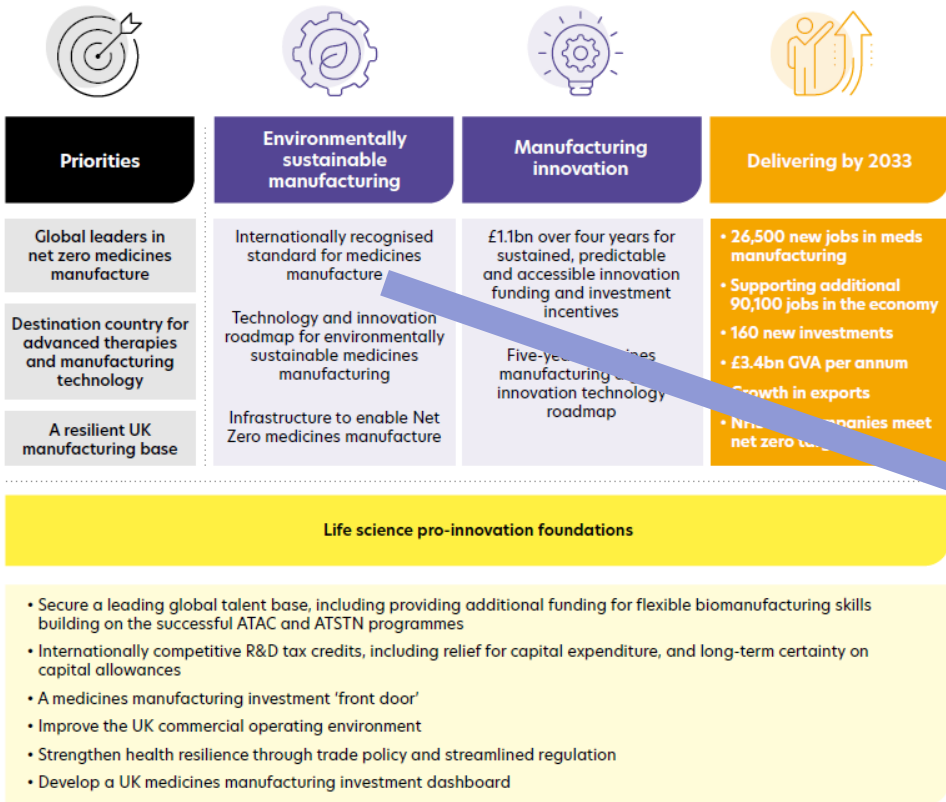
The sector sits at the intersection of healthcare innovation and cutting-edge technologies offering immense potential to transform public health, enabling people to live longer and healthier lives, and boosting productivity, while driving high-value job creation and attracting significant investment.

# UK Life Sciences

## ABPI MMIP report

Follow the green, high-tech road:

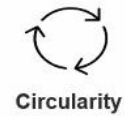
A path to UK growth, net zero and health resilience from innovation in medicines manufacturing



## Innovate UK SMMIP Program – Critical Enablers

### Scope – The Critical Enablers

Projects must also demonstrate how they will address both Critical Enablers



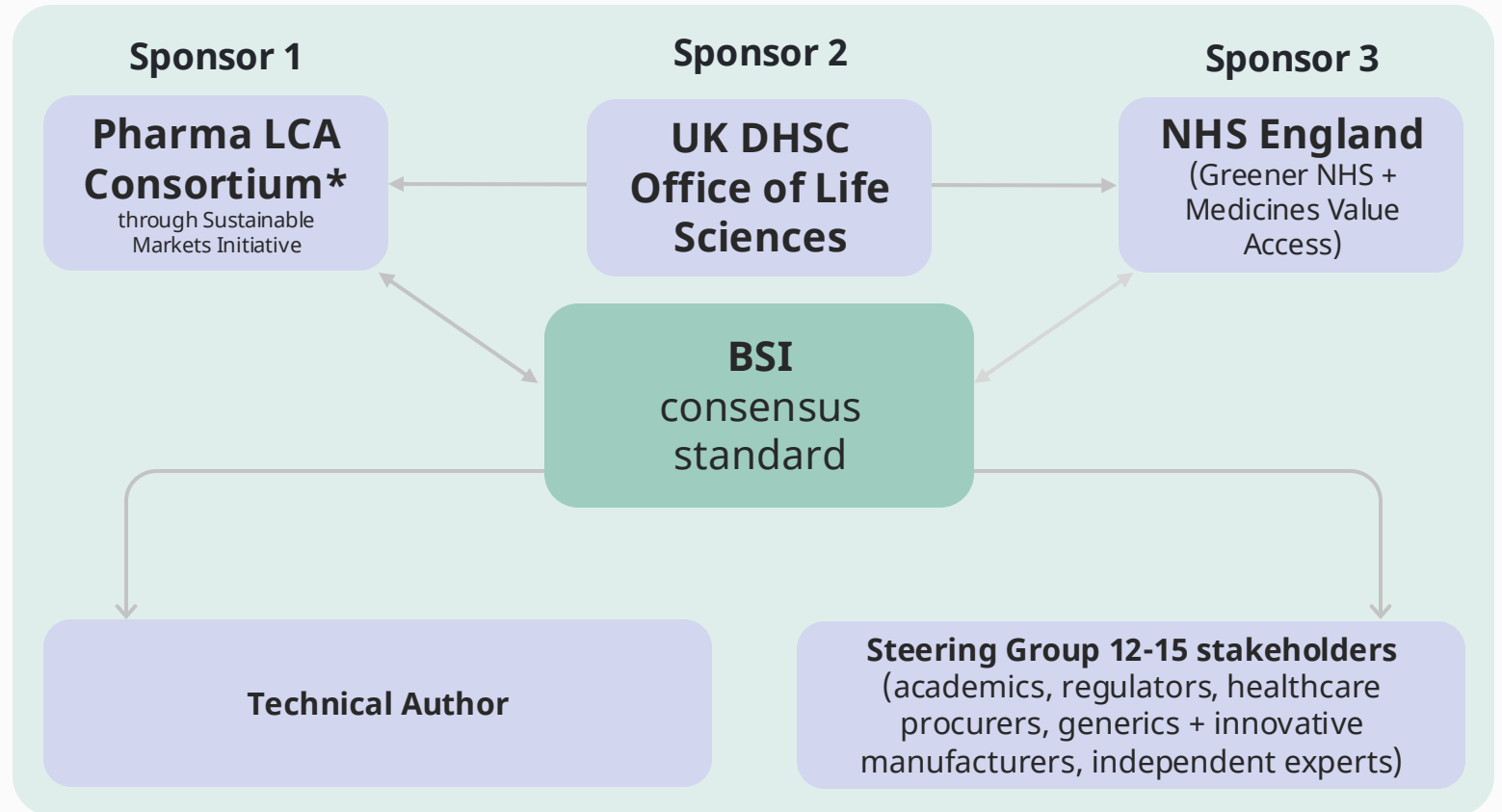
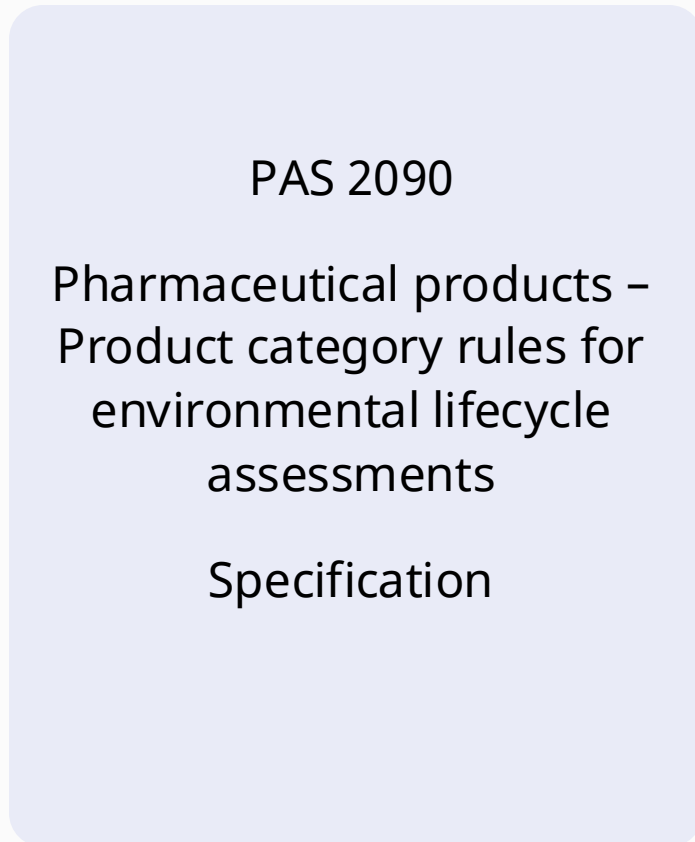
**Regulation** – an integral part of enabling the adoption of innovation in pharmaceuticals manufacturing and is sometimes considered a barrier to delivering change following technical innovation. What regulatory issues are raised by the innovation and how will the project address these?

**Measurements, Standards & Data** – with a focus on the development of common techniques to enable comparable measurement and reporting of resource efficiency metrics across the sector and supply chain, without which there are barriers to effectively measuring the impact of innovation and enabling adoption.



# Measure environmental impact of medicines - LCA

BSI is working with a multi-stakeholder, consensus-driven standard for defining and aligning terminology, methodologies, and measurement of environmental impact of medicines through lifecycle assessments (LCA).



*\*Pharma LCA Consortium – a consortium of **nine global pharmaceutical companies** have come together via the Pharmaceutical Environment Group (PEG) - with support from the Sustainable Markets Initiative (SMI)*

# PAS 2090 – UK-led, global implications

We have a diverse community of over 300 participants in the PAS Digital Hub, representing 27 countries across all regions.

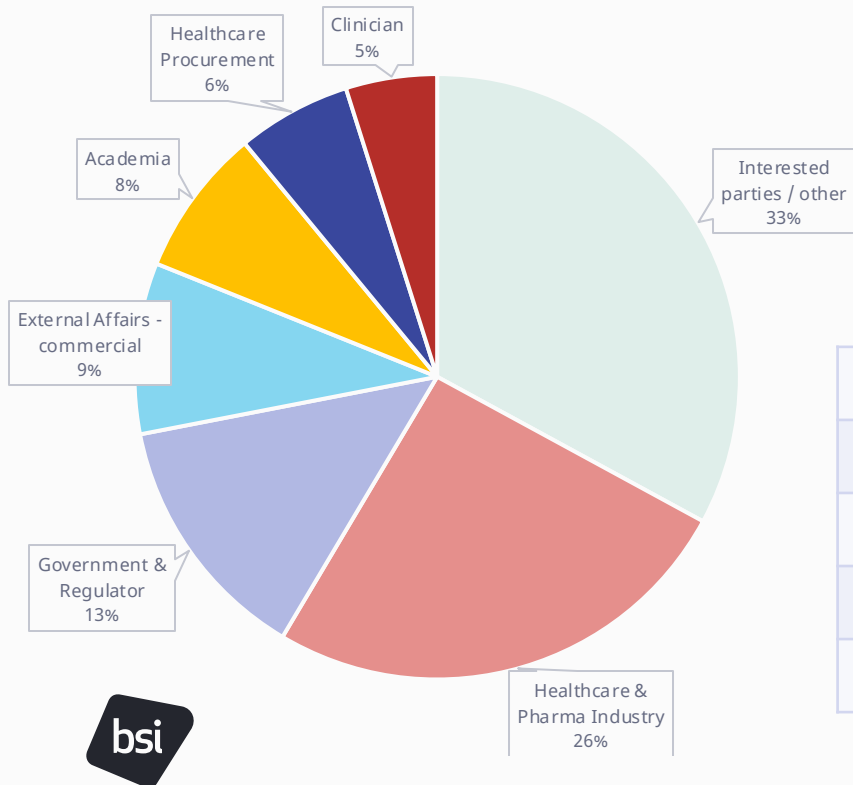
Academia

NGO/AID

Consultancies

Trade bodies

Govt & Regulators



UK	126
EU	107
Americas	51
Asia	24
Africa	2

BSI-hosted community digital hub for stakeholder engagement, awareness, education, and consultation

**UK origin → Global implications**



# Antimicrobial Resistance – antibiotics waste pollution in the environment

“Antibiotic Manufacturing Standard” and BSI Kitemark- sets and verifies criteria for measuring safe concentrations of antibiotic discharge in waste streams into the environment.

## UK National Policy



## National Procurement Policy



## Supranational Policy

UK DHSC 2024-2029 National Action Plan on AMR – [here](#) – references to the industry standard and BSI certification



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.

**NHS England antimicrobial subscription model** - responsible manufacturing requirement – Antibiotic Manufacturing Standard + BSI AMR Kitemark.

## Ensure NHS antibiotic tender compliance

Antibiotic manufacturers require BSI AMR Kitemark certification

[Find out more](#)



**UN General Assembly High-Level Meeting on Antimicrobial Resistance (AMR) Political Declaration** includes the Antibiotic Manufacturing Standard developed by BSI.





# BSI Programme Support



# Innovate UK Programme Services Overview

Through a wide range of Innovate UK programmes, support has been provided to competition winners, grant recipients and other stakeholders through standards-centric guidance and advice.

The aim is to help grant recipients **identify and prioritize existing standards** that address barriers to adopting best practices in their sector.



## Standards Landscaping and Content Research

- Understanding of relevant standards and content already in existence
- Detailed mapping and analysis of existing content
- Interactive standards landscape



## Standards Strategy

- Standards roadmap: recommendations for standards frameworks and pathways towards wider goals
- Relevant committees / working groups / steering groups.



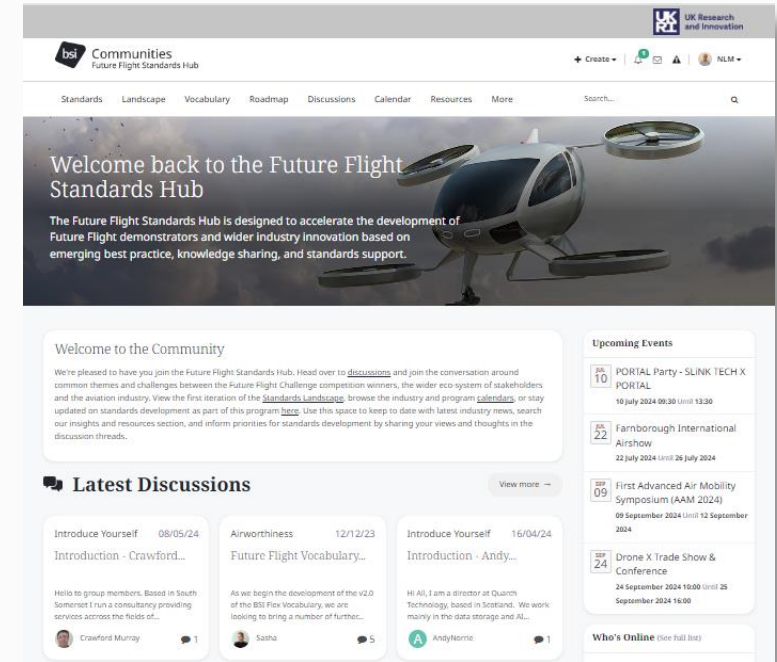
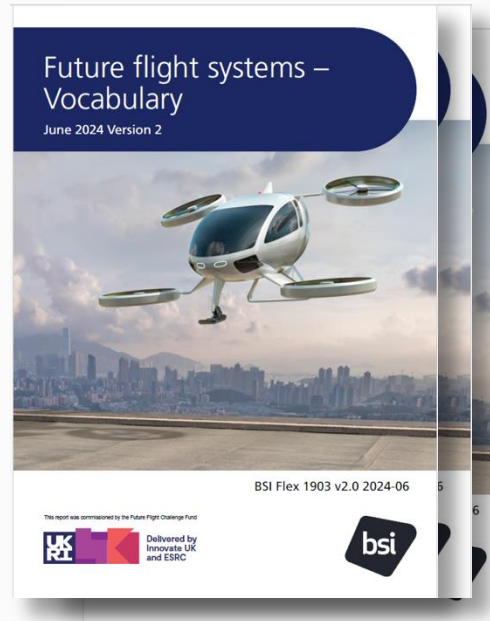
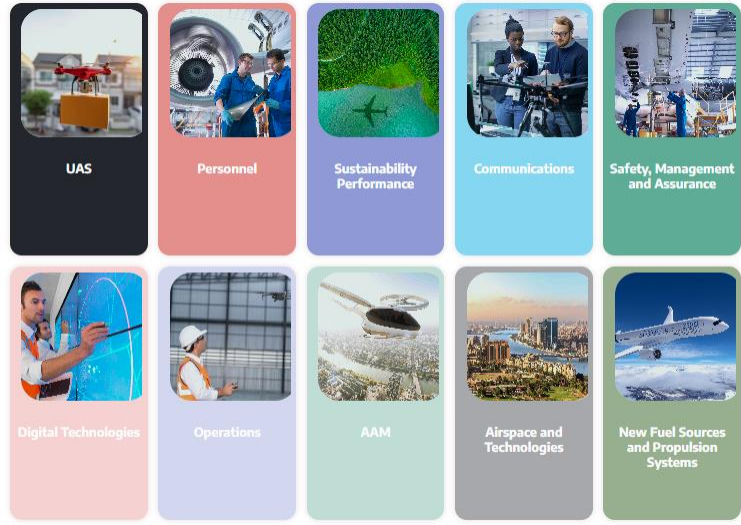
## Standards-centric Support

- Technical consultancy about existing standards
- Webinars, workshops, published material, grant recipient support, reports, thought-leadership
- Bespoke training packages



## Embed new approaches

- Marketing and Engagement
- One-to-One guidance for competition winners
- Workshops and Seminars



## Landscape and roadmap

- Interactive standards landscape
- Roadmap development – enabling industrialization

## New standards

- **Flex 1903** - Vocabulary
- **Flex 1904** - Operational Design Domain
- **PAS 1905** – Guidance for new entrants and scaleups
- **Flex 1906** – Means of compliance for SORA

## Future Flight Standards Hub

- Access and understand standards
- Explore the landscape and roadmap
- Help drive future standards development
- **Join: [future-flight.bsigroup.com/](https://future-flight.bsigroup.com/)**

# BSI's BridgeAI standards support

BSI is a strategic delivery partner of the BridgeAI programme, focused on standards and regulatory guidance, helping accelerate development/adoption of AI technologies, and reducing risks for SMEs.

Standards  
support

Standards  
training

BridgeAI Standards  
Community

Events &  
resources



# Thank You

BSI Group

389 Chiswick High Road

London, W4 4AL

+44 345 080 9000

[bsigroup.com](https://www.bsigroup.com)

