BioPhorum

Managing more with less
The Power of Platforms

CONNECT
COLLABORATE
ACCELERATE™

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BioPhorum: a co-ordinated program of industry change

BioPhorum's mission is to create an environment where our members from the global biopharmaceutical and device industries connect, collaborate and accelerate progress – for the benefit of all.

Member-led
to reflect the reality of the industry in a sales-free environment where technical discussions are paramount

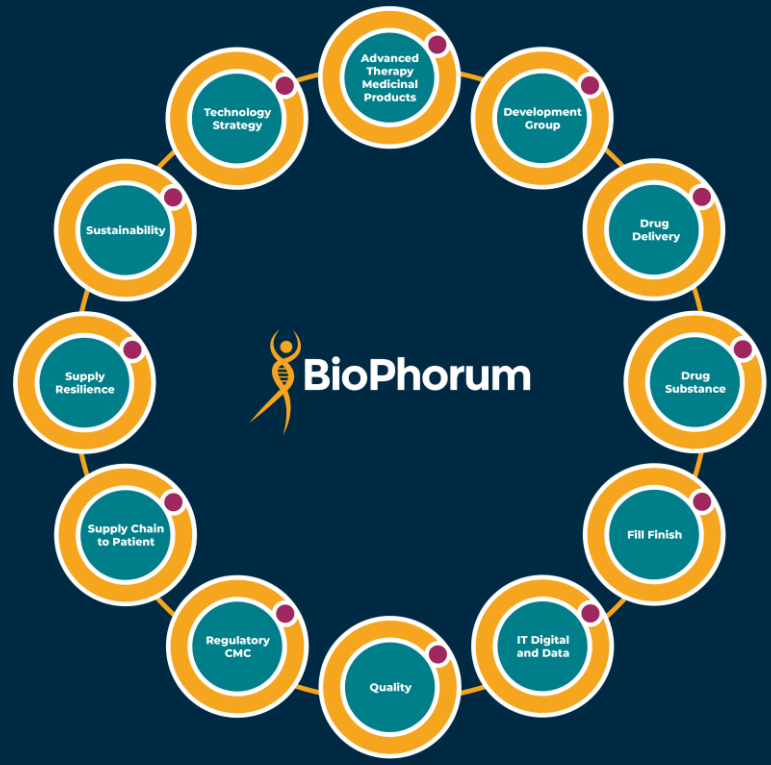
Safe and confidential
conversations with equitable contributions from all companies to build trust for sharing and collaboration

Cheaper, faster and better journeys
through our powerful proven collaboration model, allowing member companies to meet peers and share challenges

Consensus-driven
means debates leading to understanding and creativity, so we can share, learn and build the best solutions together

This allows for cost reduction, lower waste, improved productivity, better environmental performance across the value change, better investment decisions and the cost of poor decisions avoided.

There are currently 12 Phorums providing a wealth of opportunities for companies to align their interests with similarly committed organizations.



150+
member companies

120+
global programs for change

1000s
leaders and subject matter experts

150
published papers, presentations and resources in the last 12 months

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Why has BioPhorum been working on Platforms

- **The challenge**
  - ICH, EMA and the US Congress have all published CMC guidelines in the last few years mention on the concept of ‘platform’, with contrasting definitions and applications
  - This is leading to uncertainty and lack of full value realization of a potentially very powerful concept

- **The solution developed through BioPhorum**
  - Clear definitions
  - Articulation of benefits of using platform approaches
  - HOW to do it, the paper is a direct guide for implementation

Pharma industry questions FDA on platform technology designation program

Regulatory News | 23 January 2024 | Joanne S. Eglovitch

The US Food and Drug Administration (FDA) will soon be issuing guidance on its platform technology designation program, which should clear up many industry questions related to the program, asserted Phillip Kurs, regulatory counsel for FDA's Center for Biologics Evaluation and Research (CBER).

FDA's Phillip Kurs speaks at CASSS's CMC Strategy Forum

During a session at the CASSS Well-Characterized Biotechnology Products (WCBP) conference in Washington, DC on Monday, Kurs said the new designation program also formalizes the existing pathway for getting products made on novel platforms approved. The goal of the program is to facilitate the development of platform technologies that can be used to manufacture more than one drug or biological product through a standardized production or manufacturing process or processes.

Kurs said the forthcoming guidance should address some of the questions raised at the meeting, including the number of products deemed necessary to designate a platform technology, whether the program is necessary, and the level of documentation that should be submitted to get a platform technology approved. However, he declined to offer a timetable for when the guidance will be issued.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 January 2022
EMA/CVMP/IWP/286631/2021
Committee for Veterinary Medicinal Products (CVMP)

Guideline on data requirements for vaccine platform technology master files (vPTMF)

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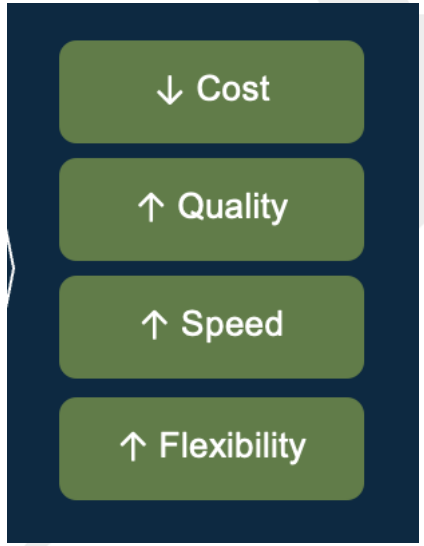
Why do it?

- Decreased costs, time, resources (personnel and material), and risks to technical and regulatory success
- Applicability of a single procedure to multiple candidate product applications, reducing repetition and redundant development activities through historical knowledge and understanding
- Simplification of optimized commercial operations, from raw material sourcing to manufacturing processes to testing, resulting in enhanced product quality and compliance
- Demonstration of growing expertise and efficiency in the development of new products



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What is a platform?

A common or standard strategic approaches, technologies, or methods, that are incorporated or utilized across multiple products. A platform is applied to a ***similar class of products (biologics)***, that are processed using ***similar principles for a similar outcome***. Well-understood platforms may leverage **data** as a scientific bridging justification **to support a platform claim** for new product candidates

Platform technologies are applied to similar candidates and processed using similar principles, equipment, components, materials, attributes, parameters and conditions for a similar outcome, with confirmed repeatability of principles.

When the method used for multiple products does not modify equipment, uses the same principles, equipment, components, materials, attributes, parameters and conditions for the same outcome, a platform technology becomes a **platform method**. A platform components, materials, parameters, conditions or attributes between products.

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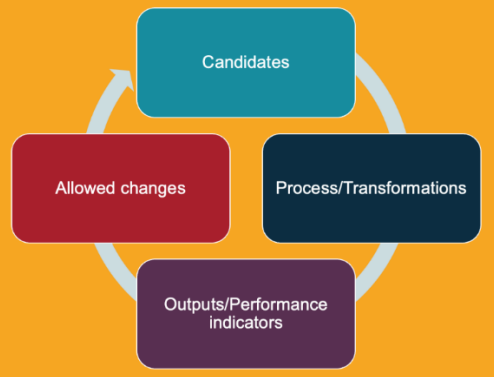
How to document a platform for regulatory acceptability?

The platform profile (PP)

A summary of the platform intended use: appropriate candidates, process and transformations taking place, outputs of the platform/performance indicators and changes allowed within the pltform



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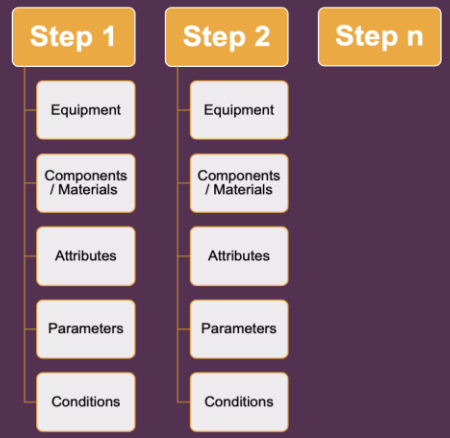
The platform description

A systematic description of the platform process steps and characteristics



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Target values and ranges

Target values and ranges are based on prior knowledge, experience and understanding of the platform and products

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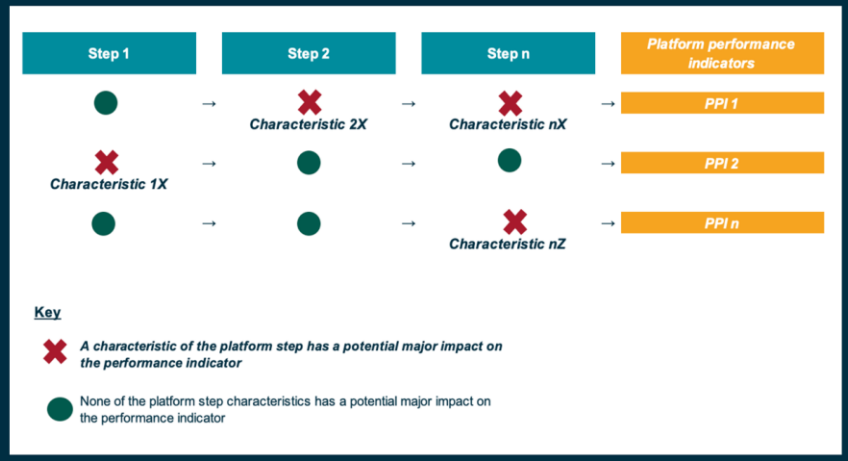
The platform control strategy

Platform characteristics that ensure control of the platform performance



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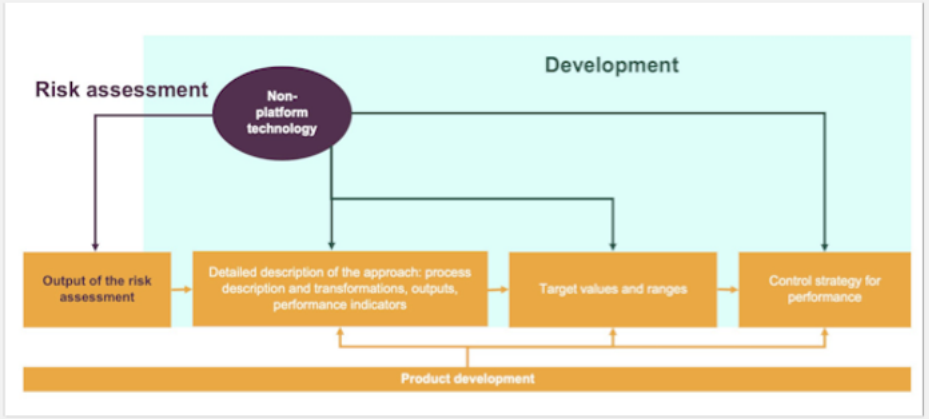
Value for the development of a new platform candidate

Non-platform procedure

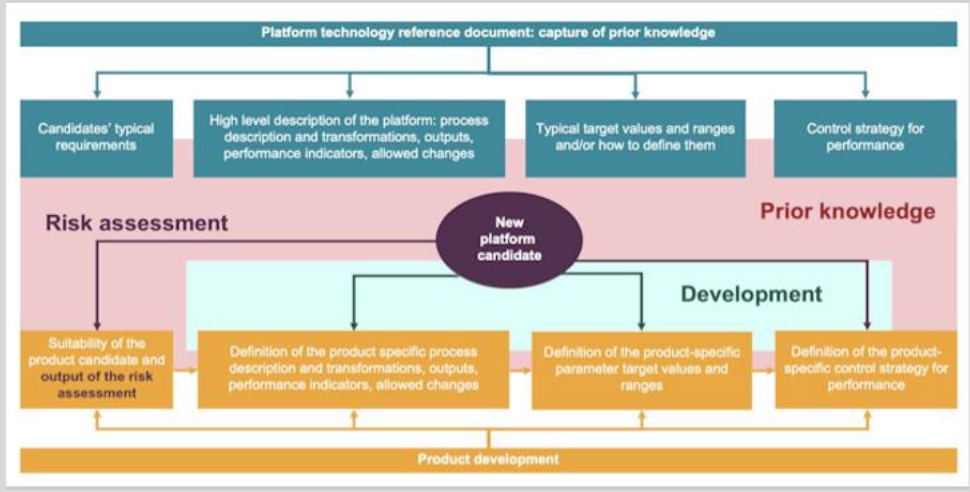


Key:

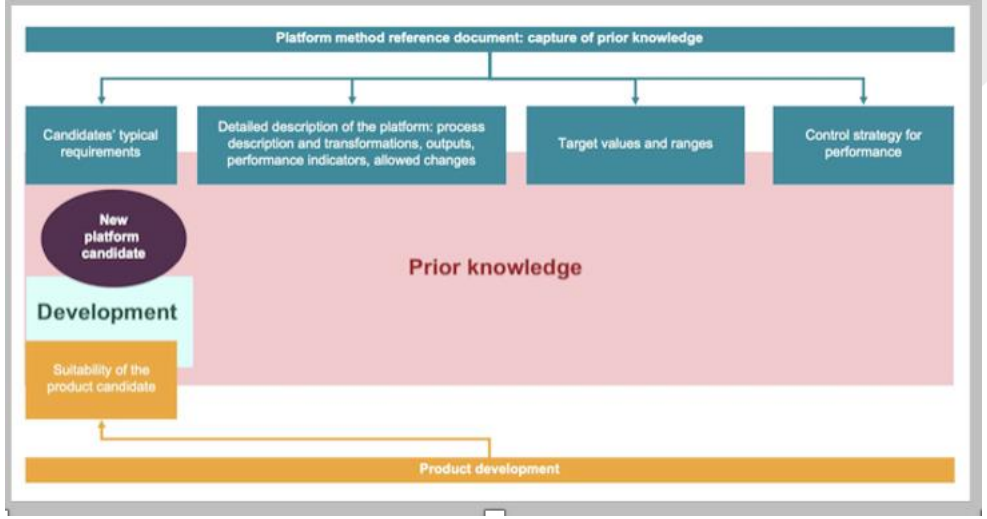
Cost, time, resources (personnel and material)

Prior knowledge - FREE

Platform technology



Platform method



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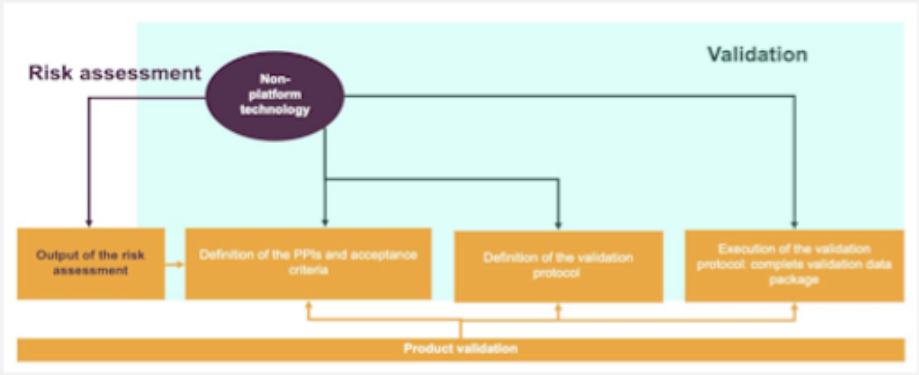
Validation for the validation of a new platform candidate

Non-platform procedure

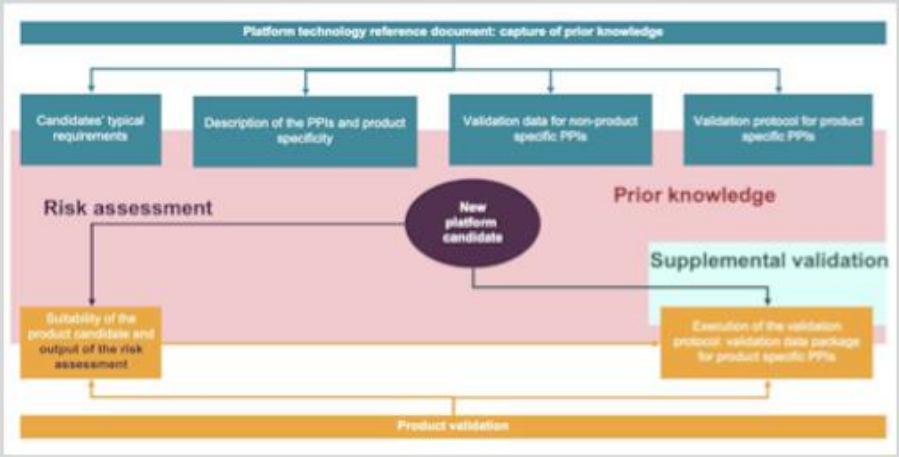


Key:

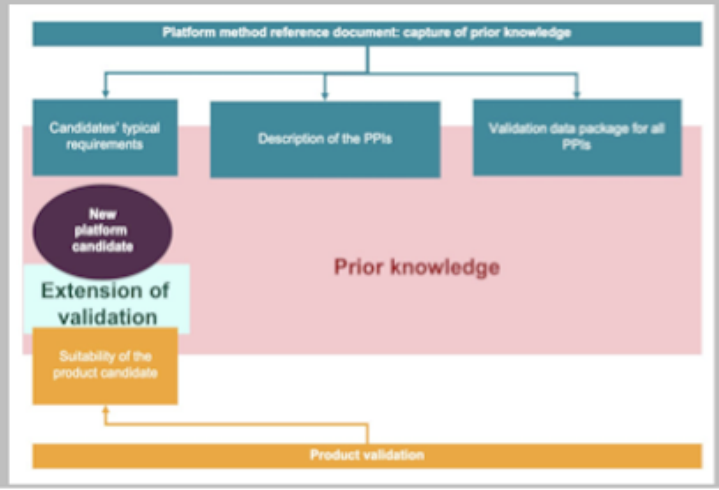
Cost, time, resources (personnel and material)

Prior knowledge

Platform technology



Platform method



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Key takeaways and specific benefits to small companies

- Through using the platform approach:
  - Prior knowledge applicable to similar products is documented in a systematic manner, based on Quality by Design principles, including development and validation activities
  - Prior knowledge can come from own experience, regulatory guidelines, literature reviews, published standards or industry collaborations
  - Development and validation activities are greatly reduced and limited to confirmation of fit of the new product to the platform
  - Higher chance of development, regulatory and commercial success

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Would you be the first ones to use the concept? NO!!!
Does it work? YES!!!

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Next steps

Your first reference:
https://www.biophorum.com/download/platforms-for-regulatory-cmc-the-necessary-definitions/

Please contact isabelle@biophorum.com for more details

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Phorum user guide and privacy policy

To read BioPhorum's policies and procedures please see our **Phorum user guide**

To learn more about how we collect, keep, and process your private information, please view **our privacy policy**

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