



A Structured Approach to Whole Process Review

Challenge

A pioneer in biotechnology for over two decades, Biogen develops, manufactures, and markets therapies for serious neurological, autoimmune and rare diseases. A globally distributed product is manufactured at multiple sites in order to manage the requirements of growing markets.

Biogen wanted a structured review of manufacturing operations with an end-to-end view of the entire manufacturing process in order to guarantee product quality and robustness.

Approach

Biogen brought together a team representing their own development, engineering, manufacturing and manufacturing science groups as well as QA functions and representatives from Contract Manufacturing Operations (CMOs). Britest facilitators led an end-to-end review of manufacturing using the visual nature of the Britest tools to document a baseline process, and facilitate the discussion and analysis of opportunities to increase robustness, optimise the process and reduce complexity.

This was the first time Biogen had approached an end-to-end technical process review in a structured and detailed way including not only technical and scientific functions but also quality and operations.

Benefits

- Bringing a globally dispersed team together enabled effective contribution of knowledge and experience.
- Technically knowledgeable Britest facilitators were able to challenge the team's process knowledge and generate deeper process understanding.
- Britest tools provided a means to structure information and quickly identify areas to gain additional expertise, helping define a detailed, prioritized and resourced action plan
- A strategic approach to achieve transformational change in cleaning processes in the industry
- The involvement of senior stakeholders generated support for applying the Britest approach for other Biogen products
- Fundamental knowledge management and cross-functional knowledge sharing and documentation

End-to-End review lets us learn from, and challenge, each other through scientific review and discussion. The result is huge learning and deeper scientific understanding, allowing teams to put the right focus on life cycle management activities and process robustness throughout the product life cycle.



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Generating value from process understanding

Key Features:

Client - Biogen

Industry - Application Area

Pharmaceuticals - Whole process review, Supply chain

Challenge

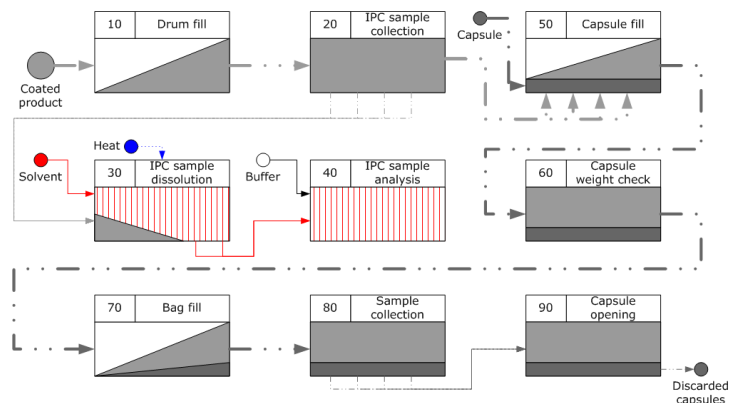
Standardise process conditions and analytical procedures across a supply chain to reduce variability

Solution

End-to-end process review by a facilitated Britest study with a cross-functional / cross-organisational team

Outcomes

Standardisation opportunities and gaps in knowledge identified and a detailed, prioritised and resourced action plan agreed



Process Definition Diagrams facilitate discussion on process knowledge

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