



IFPAC[®] - CORTONA

OCTOBER 8-11, 2023

**Centro Convegni Sant'Agostino
CORTONA, ITALY**

***An International meeting on Pharma
and Biotech Manufacturing
Innovation, Advanced Analytics and
Process Control, Informatics, Big
Data, Knowledge Management and
Global Regulatory Initiatives***

***For the Pharmaceutical,
Biotechnology and related
Manufacturing Industries***

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IFPAC Cortona 2023

October 8-11, 2023

Centro Convegni Sant'Agostino, Cortona, Italy

PROGRAM PREVIEW

The topics presented at the 2020-2022 Cortona Webinars will be expanded upon at our upcoming in-person meeting October 8-11, 2023 in Cortona, Italy. More program details and speaker announcements coming soon!

Challenges Associated with Holistic Control Strategies in the Digital Age

A robust and integrated product control strategy is the centerpiece, and arguably the most important objective, in the development of a commercial product.

Prospectively establishing functional relationships between input variables - e.g. process parameters and material attributes - and the CQAs of a drug product requires an enhanced understanding of the drug substance and drug product manufacturing processes as well as risks associated with concomitant variability that may impact those CQAs.

Manufacturing innovation increasingly relies on automation and the application of principles described in Pharma 4.0. How to convey the generation, control and management of data, and to distinguish meaningful content for regulatory assessment in an application and for inspection, becomes increasingly important for product approvals, and in particular, product lifecycle management.

You will hear from industry and regulators about the latest developments in this space. Presentations will be followed by a panel discussion intended to address questions related to the technical and regulatory challenges.

Questions & Challenges to be Addressed:

- 1) Data analytics
 - a) What do Industry foresee as the long-term expected “paradigm shift” caused by data analytics, and because the rate of change is significant, how do we avoid a “future shock” amongst Industry and Regulators?
 - b) Are global approval and post-approval frameworks able to adjust to this paradigm shift/realignment? If not, why? How/what is needed to adapt?
- 2) Pharma 4.0 Control Strategy
 - a) What does a Pharma 4.0 control strategy look like? How much is embedded in the PQS and/or described in CTD M3.
 - b) What level of information derived from data analytics is relevant/meaningful to substantiate a control strategy and for regulatory decision-making?

3) Lifecycle Management

- a) How can the generation, management and subsequent use of raw data be meaningfully conveyed to regulators (inspectors and assessors)?
- b) How does this impact assessment/inspection practices? What, if anything, needs to change?
- c) What elements of digital data (e.g. data algorithms) need to be described in regulatory applications

Regulatory Considerations for Innovation in Technology and Therapeutics.

How do we ensure an enabling regulatory environment to facilitate innovation?

This webinar will use short presentations from regulator and industry experts and a moderated panel discussion to explore future opportunities to streamline the safe and rapid implementation of innovative technologies. It will address key burning topics around innovation in pharma technical development and manufacturing.

Examples of innovative supply chains and disruptive technologies will be used to distil the key areas of need for industry and regulators to focus future discussion, such as:

- 'Point of care' manufacture of personalized, short shelf life medicines
- Innovative sterile drug product manufacturing using closed gloveless isolators for small batch production
- Manufacturing and supply of personalised ATMPs – A global challenge

Presentations and discussions will consider the importance of regulatory agility, learning from regulatory flexibility during the pandemic and how similar approaches might continue in the future.

Building Toward Future Pharmaceutical Manufacturing Through Adoption of Advanced Manufacturing Technologies

We will discuss new advanced manufacturing platforms with respect to its importance of building a robust, flexible, and agile drug supply chain, as well as challenges and opportunities related to its adoption for commercial pharmaceutical production. This is intended to provide an update on regulatory aspects of advanced manufacturing and to identify issues to be discussed in sufficient details in Cortona 2023 F2F meeting:

Topics Will Include:

Experience in Pharmaceutical Innovation from the US FDA Perspective

This topic area will describe FDA experience in pharmaceutical manufacturing innovation, discuss technical and regulatory challenges related to development, implementation, and regulatory assessment of new technologies, and explain current FDA/CDER's effort to address these challenges.

Experience in Pharmaceutical Innovation from the EU Perspective

This topic area will describe EMA experience in pharmaceutical manufacturing innovation, discuss technical and regulatory challenges related to development, implementation, and regulatory assessment of new technologies, and explain current EMA's effort to address these challenges.

Opportunities and Challenges to Innovation and Harmonization for Pharmaceutical Quality Manufacturing from Industry Perspective

This topic area will describe the journey of ICH, sharing case studies with respect to global harmonization of control strategies (successes and opportunities), and the impact to new technology and innovation. It will also illustrate how new normal opportunities that emerged during the COVID-19 pandemic could expedite global collaboration and harmonization with respect to increasing innovative manufacturing opportunities.

ADDITIONAL TOPICS WILL INCLUDE:

- Big Data, Artificial Intelligence and Machine Learning for Pharma
- Emerging Technologies: Cell and Gene Therapies
- ICH: Quality Guidelines Update
- Hot Topics: Nitrosamines and More Coming for 2023!

We look forward to presenting the latest updates and discussing challenges, opportunities, and solutions during roundtables and networking events throughout the IFPAC-Cortona Meeting.

REGISTER TODAY!

<https://ifpaccortona.org/IFPAC-Cortona/website/attendee-registration>