DAY 1

1. *The Regulatory Approach to AI: Good practices for using AI in drug manufacturing, Toni Manzano – Aizon, IntelligentGxP Manufacturing & PDA Biomanufacturing IG*

Artificial intelligence is entering the pharmaceutical shop floor faster than the rules meant to govern it. Manufacturers are already using machine learning and, increasingly, generative models to support process monitoring, decision making and quality operations, while regulators on both sides of the Atlantic are still defining what trustworthy AI looks like in a GMP environment. The EU and the US are not converging on this question. The EU AI Act and the incoming Annex 22 take a restrictive, GMP anchored view that limits generative and adaptive models in critical applications, while the FDA's draft guidance applies a broader, risk based framework across the entire product lifecycle, with more flexibility on model type and stronger emphasis on continuous credibility assessment.
For companies operating globally, this divergence is not a theoretical problem. It shapes how a model gets validated, what evidence an inspector will expect to see, and how much latitude a site actually has to deploy AI in a critical process. This talk builds the technical grounding needed to make sense of that divergence, explains why guardrails belong around the AI system rather than inside the model itself, and sets out what good practice looks like today for using AI responsibly in drug manufacturing, in a regulatory landscape that is still being written.

2. *Redefining GMP Audits through Agentic AI , **Gabriele Gori - CHIESI***

This presentation concerns an AI-powered GMP Audit platform that operates to support auditors in the end-to-end audit process, based on regulatory documentation, process data, and real-time signals.
Built on LLMs specialized in EMA/FDA regulations and regulatory knowledge, it helps creating the audit agenda and specific questionnaires, analyzing the responses and data collected and identifying and reporting potential non-compliance exposures , strengthening regulatory readiness, and proactively enabling data-driven CAPAs.
At the core of its innovation lies an agentic system : autonomous AI agents that govern the process lifecycle, orchestrate tasks, analyze evidence, and interact in natural language with Quality functions and Auditors.
The same agents continuously monitor and update the regulatory references and other sources of information underpinning the knowledge base, ensuring state of the art, predictive audits fully aligned with the evolving regulatory landscape"

3. *From GenAI to Operational Value: Designing Reliable Agents in GxP Environments — Real-World Case Studies, **Niccolò Rosini & Claudia Mandola – GSK***

This presentation explores the design and application of Generative Artificial Intelligence agents to real use cases at the GSK pharmaceutical manufacturing sites, like Rosia. In a regulated environment characterized by high document complexity, articulated manufacturing processes and stringent compliance requirements, GenAI agents can become a concrete enabler to transform available knowledge into operational value, improving quality, efficiency and decision-making.
The discussion will focus on examples of GenAI agents designed to understand context, apply predefined rules, query selected documentary sources, correlate information across different domains and support users in performing complex activities. In pharmaceutical and GxP environments, this requires a rigorous methodological approach based on controlled sources, information traceability, clearly defined operational boundaries, explicit management of uncertainty and human oversight over final decisions.
Implementation areas include as alarm recognition and contextualization, monitoring of deviations related to specific products or manufacturing processes, and process mapping. In these domains, dedicated agents can help operators, technical teams and Quality functions interpret equipment signals more rapidly, as well as systematically analyze deviations, recurrences, patterns and critical areas. At the same time, they can facilitate the collection, synthesis and structuring of technical information to support more effective process understanding and continuous improvement.
A central element of the presentation will be the development of robust and reliable agents in a regulated environment. The key principles applied in the real case studies will be discussed, including accurate definition of scope, clear delimitation of the agent's responsibilities, use of approved sources, prevention of unsupported inferences, generation of verifiable outputs and preservation of human control over decision-making steps. In the pharmaceutical context, the value of GenAI does not lie only in speed of response, but in its ability to produce outputs that are consistent, explainable, verifiable and aligned with quality expectations.
Finally, the presentation will address the conditions required to scale these tools within a manufacturing site, including governance, user training, integration with existing processes and data management. It will highlight how GenAI agents, when designed with methodological rigor and applied to real operational problems, can become a strategic enabler for building pharmaceutical sites that are smarter, more efficient, more collaborative and increasingly quality-oriented.

4. ***How AI, risk and people re-skilling are reshaping quality , Salvatore Di Nottia & Michele Simone, Bracco Corporate Quality Management***

The increasing adoption of automation and digital technologies in pharmaceutical manufacturing requires Quality Management Systems (QMS) to evolve accordingly. Traditional quality approaches must adapt to support more complex, data-driven, and dynamic environments while maintaining compliance and patient safety.
This presentation discusses how Artificial Intelligence, when embedded within a robust Quality Risk Management (QRM) framework, can support modern quality systems in automated and digital factories. The session outlines potential applications of GenAI to enhance consistency, efficiency, and decision-making across key quality processes, without compromising regulatory expectations.
Practical case studies will illustrate how AI can complement established quality practices, highlighting benefits, limitations, and governance considerations essential for implementation in GxP-regulated environments.

DAY 2

1. ***When AI Enters Decision-Making, Who Remains Accountable? Rethinking Decision Governance in AI-Augmented Quality Systems, Damiano Dragone, Pharma Quality/Compliance & GenAI Governance Advisory, Dragone Consulting.***

Artificial intelligence is rapidly entering quality and manufacturing processes, from deviation management to batch release and change control. But while systems are evolving, decision governance is not. Quality systems were designed for decisions that are human, linear and fully reconstructable.
AI changes this paradigm. Decisions become distributed, co-constructed between humans and systems and increasingly difficult to explain, trace and defend. This creates a fundamental gap: decisions are still expected to be fully accountable but the way they are formed is no longer aligned with that expectation.
The real risk is not the technology itself but the loss of clear ownership, accountability and defensibility of decisions. This session introduces a shift from process control to decision control, proposing a structured way to govern AI-supported decision-making in regulated environments. Through practical examples, it will show how organizations can adopt AI while maintaining full control over their most critical decisions.

2. ***Designing the Road to Automated Quality Control, Carina Seitz & Ines Schaider - TAKEDA***

This joint presentation outlines Takeda's journey from a fully manual, cell-based potency assay towards a digitally enabled and ultimately end-to-end automated solution in vaccine quality control. As a critical QC method with high manual effort and inherent variability, the assay represents an ideal candidate for stepwise digitalization and automation.
The presentation connects practical, already deployed digital building blocks with the conceptual design of a future integrated automation setup. We will share how we are leveraging (i) automated counting of viral foci, (ii) digital twin and simulation concepts, and (iii) digital workflows via EBR-based documentation to de-risk design choices, improve process understanding, and drive cross-functional alignment. Building on an existing prototype and an integrated automation concept orchestrated by a central software layer, we will discuss selected decision points and trade-offs considered during the current design phase, including system architecture and integration strategy, digital workflow design, and selected aspects of data integrity and audit readiness.

3. ***Automated Clearance & Manufacturing Intelligence: evolving from vision systems to digital and cognitive manufacturing, CORIMA Marchesini – Sea Vision***

Current pharmaceutical production models and emerging vision technologies can be effectively integrated to enhance process intelligence.
This integration helps prevent deviations, reduces the risk of human error, and strengthens operational traceability.
Achieving this alignment requires OEM to take on greater responsibility by equipping production and packaging lines with advanced systems capable of capturing relevant images and videos of the manufacturing process, operator activities, and machine behavior.
One of the application examples is the automation of line clearance verification, which is systematically performed during changeover operations. Similarly, the combination of these advanced systems with structured visual data

acquisition and advanced analytics enables key elements of cognitive manufacturing, such as real-time insights and adaptive decision-making, ultimately driving continuous improvement across pharmaceutical production processes.

4. ***A Digital Transformation Journey: from Data to Better Decisions in Manufacturing,***
Marcorosario Cusmano - Merck & Emmanuele Dicerto - KOERBER

The first part of this presentation explores the Digital transformation roadmap of a pharmaceutical site, applied to an end-to-end manufacturing process.
The discussion will start showing an interconnected plant, and particularly the implementation of the MES system in a pharmaceutical plant, from the incoming of raw materials to the finished products, linked to all satellite systems.
Concrete examples of process digitization will be presented, illustrating the shift from a paper-based system to a fully digital infrastructure. It will examine how all enterprise information systems (GLIMS, SAP, SCADA) interface with the MES, emphasizing an integrated end-to-end data flow and traceability of information across the entire manufacturing chain. The discussion will also address how digital management, enabled by interoperability between systems, adds value in terms of regulatory compliance, product quality, and operational efficiency, with impacts on compliance, cycle times, and error reduction.
The second part focuses on how data can support decision-making by enhancing analysis capabilities across manufacturing operations. In this context, the integration of execution, data, and process context enables the transformation of information into actionable insights, improving visibility, consistency, and responsiveness to deviations.
This approach allows a shift from simply "recording what happened" to "understanding what is happening," enabling faster, more informed, and risk-aware decisions.
Advanced analytics, including AI where appropriate, can further enhance this capability. However, the primary value lies in the availability of structured, contextualized data that supports performance monitoring, deviation analysis, and decision-making processes, with a focus on quality, compliance, and overall production efficiency.

5. ***Beyond Traditional Handover: Accelerating Product Realization with Digital CMC and Unit Operation Models, Duccio Bianciardi & Ilaria Mori - GSK***
This presentation explores the impact of integrated digital platforms and innovative modelling applications in accelerating pharmaceutical development and enhancing manufacturing efficiency. Industry increasingly leverages advanced data engineering and sophisticated data platforms, moving beyond traditional data collection systems to promote a quicker data-driven decision-making process. Concrete examples of digital platforms and modelling will be able to demonstrate how these instruments could improve value extraction and product control from Early Development to Manufacturing.
The discussion will start showcasing how digital platforms empower advanced analytical techniques such as Drug Substance process development. This approach utilizes multivariate data analysis and machine learning algorithms to improve drug substance properties, predict manufacturability, and guide material selection with greater precision and speed. Clustering approach will guarantee a earlier identification of critical quality attributes (CQAs) and critical process parameters (CPPs), thereby streamlining the development pathway.
Further along the pipeline, the presentation will discuss the application of process and unit operation modeling for Drug Product use cases. Digital platforms provide the computational power and data infrastructure necessary to build and validate mechanistic and data-driven models (i.e., mixing, lyophilization and nanosuspension formulation) and robust the entire manufacturing processes.
Furthermore, a critical aspect is product stability. We will show how accelerated stability modeling and innovative statistical approaches are able to predict long-term stability from limited short-term package of data, informing data-driven End of Shelf-Life specifications, ensuring product quality and patient safety.
Finally, real-world manufacturing case studies will illustrate tangible benefits. The presentation will tackle future challenges: AI/ML integration for autonomous manufacturing, the evolution of regulatory landscapes and the need for skilled talents. Ultimately, digital platforms represent a strategic investment for a more efficient, collaborative, and value-driven pharmaceutical future.

6. ***AI-Augmented Deviation Investigation: from manual variability to structured, auditable intelligence, Vivek Seth, Simtra BioPharma Solutions & Marco Iacobelli, InfiniteVision***

Pharmaceutical quality investigations are inherently complex, requiring rigorous analysis, consistency, and full traceability. However, traditional approaches are often manual, time-consuming, and subject to variability, limiting both efficiency and reproducibility.

Our presentation describes the successful completion of an AI-driven transformation program aimed at enhancing deviation investigation processes through the introduction of specialized AI agents.

During the implementation, we designed, developed, tested and deployed an AI agents focused on document quality and compliance assessment. The agent combines two main features:

- enabling structured review of deviation reports, improving clarity, consistency, and linguistic quality
- systematically evaluation of investigations against predefined quality rubrics and internal checklists, identifying gaps, inconsistencies, and areas for improvement.

To ensure robustness and regulatory alignment, the solution was built around deterministic, auditable logic and strict evaluation schemas, enabling transparent scoring of investigation quality across multiple dimensions. The approach integrates structured data extraction, rubric-based assessment, and explainable outputs, ensuring that every recommendation is traceable and grounded in explicit criteria.

The implementation followed a structured methodology, from requirements alignment and agent design to PoC development, validation on real cases, and full industrialization, complemented by user training and change management activities. This phased approach ensured both technical reliability and effective adoption across the organization.

The outcome of the project demonstrates how AI can augment human expertise—rather than replace it—by increasing consistency, reducing review time, and improving the overall quality of investigations. This creates a solid foundation for more advanced capabilities in subsequent phases, ultimately enabling a more scalable, data-driven, and continuously improving quality system.

7. *Overcoming barriers when moving from paper to digital GMP related documentation - Janin Stratmann-Selke, Abbott & Ecolab*

8. *AI-Driven Digitalization of Design Qualification (DQ), Pablo Munoz Pierattini - CSV & Chemelectiva*