

## **PDA Shaping the Future of Vaccines Workshop Summary Report from the PDA BioManufacturing Conference 2025**

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Vaccines have saved 93.7 million lives from 1974 to 2024, combating diseases like measles, polio, meningitis, and HPV.

COVID-19 vaccinations substantially altered the course of the pandemic, saving tens of millions of lives globally **(1)**. Innovative development strategies are essential to strengthening the vaccine ecosystem by accelerating research and development, improving manufacturing efficiency, and enhancing global access. They enable faster adaptation to emerging health threats through the use of platform technologies, digital tools, and model-based approaches. By fostering regulatory agility, cross-sector collaboration, and sustainable production, these strategies ensure that vaccine development remains responsive, resilient, and capable of delivering high-quality, equitable immunization solutions worldwide.

Organized by the Parenteral Drug Association (PDA) in collaboration with Vaccines Europe, the “*Shaping the Future of Vaccines*” workshop brought together stakeholders from regulatory agencies, academia, the vaccine industry, and global health organizations to discuss key trends, challenges, and opportunities in innovative vaccine development and manufacturing.

The one-day, in-person workshop provided a comprehensive overview of the evolving vaccine landscape and explored strategies for sustainable innovation and competitiveness in Europe. Sessions covered a range of topics, including regulatory perspectives on accelerated vaccine access, model-informed vaccine development, platform-based approaches, and the integration of new technologies to enhance efficiency and quality in vaccine manufacturing.

Through presentations from regulatory authorities, non-governmental organizations (NGOs), and industry leaders, as well as interactive panel and table discussions, participants examined how emerging regulatory frameworks, innovation in manufacturing, and cross-modality strategies can help strengthen European and global vaccine ecosystems. Case studies from companies showcased practical examples of innovation in vaccine production and packaging, illustrating how regulatory and sustainability goals can be effectively aligned.

The workshop served as a platform for open dialogue and collaboration between public and private sectors to identify key regulatory and technical needs to support continued advancement in vaccine science and manufacturing.

### **Setting the Scene: Multi-Discipline Innovations**



At the beginning of the workshop, presentations from regulators (European Medicines Agency - EMA), industry representatives, and a global health NGO (Coalition for Epidemic Preparedness Innovations - CEPI) highlighted the importance of innovative approaches and strategies in vaccine development for the acceleration of vaccine access, pandemic preparedness, and strong immunization systems.

In this context, key requirements for rapid vaccine deployment should include multidisciplinary considerations, such as innovative clinical trial design, CMC development, manufacturing site preparation, streamlined and harmonized regulatory approvals, and a thorough vaccine supply chain strategy. CEPI provided examples of its focus on driving incremental, well-recognized, paradigm-shifting innovations, including pre-reviewed documentation, the use of platform data, immune correlates of protection, and benefit-risk assessments.

The speakers underscored lessons from COVID-19 that should be leveraged and applied to aspects of product development to enable early vaccine deployment **(2)**.

For instance, GSK reported on the usefulness of an innovative clinical design approach in the pandemic, based on model-informed vaccine development (MIVD). MIVD tools, such as Quantitative Systems Pharmacology (QSP), in silico trials, and digital twins, were effectively used to accelerate vaccine development. During the workshop, examples were shown by GSK on Phase 2/3 dose selection using digital twins and vaccine end-of-shelf-life predictions using QSP and CMC modeling. Besides de-risking clinical strategy and execution, they concluded that such studies can support CMC development; for example, they can provide a sound rationale for the justification of potency specifications grounded in appropriate dose-finding studies.

The need for regulatory flexibility, readiness, and collaboration (including regional networks) was emphasized. EMA updated on the remit of its Emergency Task Force (ETF) and presented the regulator's view on the coordinated approach needed to accelerate vaccine development and marketing authorization. The presentation also noted that EMA promotes advancements such as variant-proof vaccines, mucosal vaccines, human challenge studies, and regulatory tools, such as rolling reviews and accelerated assessments, to enable faster vaccine access. Through the work of the ETF, EMA supports vaccine development, evaluation, and monitoring, and provides reliable information and scientific advice during emergencies. Moreover, the ETF's scientific advice to developers has recently expanded, with the involvement of clinical trials and ethics experts from EU Member States to cover aspects of clinical trial authorization. Additionally, several activities are in progress at the EU level, involving the EMA ETF, to make the clinical research environment in the EU more attractive and enhance preparedness. Finally, EMA aims to enhance transparency, combat misinformation, and engage healthcare professionals and patients to improve vaccine trust and uptake.

Vaccines Europe presented its Pipeline Review 2024, which underlined innovation happening within the vaccines industry to address global health threats such as climate change, antimicrobial resistance (AMR), zoonoses, and pandemic preparedness **(3)**. The presentation also noted that the time between marketing authorization approval and the date on which funding was effectively implemented (either via National Immunisation Programme (NIP) or reimbursement) varies between two and six years, which creates access discrepancies in Member States, as the decision to include new vaccines in the NIPs is under the remit of the national authorities **(4)**.

The assembled speakers continued sharing their considerations in the format of open discussion with audience:

**Q: What are the key factors needed to enable acceleration?**

- **Platform knowledge and models:** Using platform knowledge and models as a starting point to streamline vaccine development facilitates early interaction with regulators and provides sound justification for their applicability for specific products.
- **Modeling tools and model-informed vaccine development:** Data-driven modeling from preclinical stages through development, the use of advanced modeling tools, and cross-functional collaboration to optimize vaccine development and regulatory processes are critical enablers for accelerating vaccine innovation. *Post-meeting note: Depending on the criticality of these models, the required supporting data will vary, and regulators are open to discussion on a case-by-case basis.*
- **Integrated data frameworks:** A robust system connecting discovery and development data is necessary to support informed decision-making. Translational research and improved funding opportunities, including for academia, would benefit European as well as global preparedness for future emergencies.

**Q: In the scenario of 100 Days Mission presented by CEPI, when do regulatory agencies intervene?**

- The position of CEPI is that there is a need for close collaboration between regulatory agencies and industry along the whole process of vaccine development **(5)**. During the COVID-19 outbreak, this was exemplified by the COVAX Regulatory Advisory Group, consisting of 13 regulatory authorities co-chaired by CEPI and WHO, which served as a forum for regulators to discuss important regulatory issues flagged by

industry. Looking forward to key areas that will become important in the future, a real accelerator will be the use of artificial intelligence (AI) to analyse and present data in real time and enable rolling data review tools (according to CEPI, this will happen in the next five years).

**Q: What are the countermeasures to be put in place to overcome the current geopolitical challenges?**

- **Flexible global supply chains:** Vaccine supply chains should remain globally interconnected and adaptable, including flexibility in sourcing and managing raw materials.
- **Diversified manufacturing network:** Maintaining multiple manufacturers worldwide strengthens resilience. The vaccines ecosystem should expand manufacturing portfolios per disease and support early-stage development (up to Phase I/II) across several producers to mitigate shortages.
- **Risk assessment and alert systems:** Ongoing efforts in Europe aim to establish comprehensive risk evaluation and mitigation strategies for vaccines and other modalities. Further development of effective surveillance, including diagnostic capacity and early-warning systems for emerging diseases, is needed globally, and recent improvements in the EU are acknowledged.
- **Socioeconomic modeling:** Incorporating socioeconomic analyses enhances communication strategies and facilitates more evidence-based political dialogue around vaccine policies.

**Q: What is needed to overcome the current distrust and diffuse vaccine hesitancy?**

- **Coordinated communication strategy:** Stronger alignment between regulators, industry, and other stakeholders is essential to counter vaccine hesitancy by leveraging decades of existing effective communication experience.
- **Proactive monitoring:** Systematic screening of social media is needed to identify and respond early to emerging misinformation, while amplifying positive narratives supported by independent, real-world evidence.
- **Transparency and trust:** Sharing accurate safety data, such as true incidence rates of adverse events, helps build credibility and public confidence.

- **Preparedness for politicisation:** Institutions must anticipate and be ready to address the politicisation of health and vaccination issues, ensuring timely, fact-based responses.

### **Chemistry, Manufacturing and Control (CMC) considerations:**

The panel of speakers provided their perspectives on the CMC, clinical, and regulatory tools to shape the next generation of vaccines.

### **EU Regulatory Framework (quality perspective) - EMA:**

- The EU regulatory framework supports vaccine innovation through early engagement, scientific advice, and flexible quality approaches.
- Key mechanisms led by EMA, such as the Innovation Task Force, Quality Innovation Group, and Emergency Task Force, enable continuous dialogue from research to authorization and beyond.
- Lessons from the COVID-19 response, including the use of rolling reviews and conditional authorizations, are shaping long-term regulatory evolution for new technologies like mRNA platforms.
- EMA's collaboration with global partners fosters regulatory convergence (e.g., EMA-Food and Drug Administration (FDA) Parallel Scientific Advice, International Coalition of Medicines Regulatory Authorities (ICRMA) Assessment pilot, EMA OPEN initiative), while EU strategies on life sciences and medical countermeasures aim to future-proof the system and maintain Europe's leadership in vaccine innovation.

### **Innovation in cross-modality strategies – Johnson & Johnson:**

- Innovative control strategies can strengthen vaccine development by integrating scientific understanding with regulatory flexibility.
- Starting from early development, a structured Quality by Design (QbD) approach ensures that control strategies evolve consistently from Phase I to commercialisation.
- Leveraging existing platform knowledge during vaccines development and across modalities reduces complexity and accelerates progress.
- Robust analytical characterisation of potency and comparability supports regulatory alignment and potential waivers for lot-to-lot studies.

- Overall, knowledge sharing, data integration, and early engagement with authorities underpin innovation and reliability in modern vaccine control strategies.

### **Innovation through Artificial Intelligence (AI), Machine learning (ML), and Modeling - GSK:**

- Digital innovation, including AI, ML, and product and process modeling, is transforming vaccine manufacturing and development. The regulatory framework should adapt to these new challenges and technologies while ensuring product quality and patient safety.
- Use of AI in CMC includes product and process development, process control, data trending and deviation analysis, report generation, etc. For example, hybrid digital twins and computational modeling approaches can be used to improve process design, scale-up, and real-time control.
- GSK emphasised the importance of having appropriate data infrastructure, model-use justification, and flexible, risk-based regulatory frameworks that enable science-driven vaccine innovation. Collaboration between regulators, industry, and academia remains essential to embed these concepts in manufacturing practices.

The workshop's participants and speakers then had an interactive discussion around the following questions:

#### **Q: How can stakeholders support translation from academia to mainstream vaccine development?**

- Regular scientific dialogues between regulators and academia, such as the EMA ETF workshops, are effective in supporting the translation of academic innovation into mainstream vaccine development.
- For translation to take place, the key challenges remaining are the need for industry to support further development and the lack of incentives or financial support towards research bodies, especially in the current climate.

#### **Q: What initially blocks innovation in vaccine development?**

- Innovation in vaccine development is often hindered by the pressure to move quickly during discovery and early development, leaving little room to implement new approaches.

- In a pandemic situation, the rapid introduction of new platforms and technologies becomes particularly challenging due to time constraints.
- To overcome these barriers, it is important to work during the “normal time” (preparedness) on accelerating the development of innovations to be ready for the next epidemic/pandemic.

### **Q: How AI has been used?**

- AI and ML are reshaping nearly every stage of the drug lifecycle, from early discovery and research to manufacturing and post-marketing activities. In Europe, as in other regions, the regulatory framework for AI is evolving rapidly, particularly with the EU AI Act, which came into force on August 1, 2024 **(6)**.
- EMA published the scientific guideline *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle* in September 2024 on the use of AI following the open consultation process **(7)**.
- Stability modeling to predict product shelf life represents an example of how data-driven approaches can be integrated into the regulatory framework.
- Positive experiences have been reported by the industry in sharing AI-based innovations with regulators, who are increasingly aware of emerging technologies; however, further conversion of these advances into formal guidelines is needed to ensure global consistency and broader adoption across regulatory bodies and inspection practices.

### **Case-examples of Innovation in Manufacturing Facilities:**

To ensure connection between strategic considerations and practical solutions, the following sessions focused on real-world case studies from companies such as HIPRA and Sanofi, spotlighting various technology platforms.

#### **Multi-technology platform vaccines facility - Sanofi:**

**Challenges:** Sanofi reported that vaccine development involves multiple platforms (recombinant proteins, viral particles, mRNA) with uncertain clinical outcomes and variable yields. Facilities must handle fluctuating demand and rapid shifts in production priorities while ensuring regulatory compliance.

**Objectives of Next-Generation Facilities:** New vaccine facilities must enable fast product launches, support multiple process platforms, and ensure efficient capacity utilization. The goal is to reduce investment risk, shorten time-to-market (including during pandemics), and transition from fixed to variable cost structures.

**Design Principles for Agility:** Sanofi's *Modulus* concept was presented as a model for innovation in manufacturing. It integrates:

- Flexible, expandable, and multiproduct ballroom designs
- Standardized modular equipment
- Single-use and plug-and-produce technologies
- Digital twins and pilot labs for simulation and optimization
- Optional partitioning allowing rapid reconfiguration of suites to run parallel production lines

**Implementation:** The *Modulus* facilities in France and Singapore exemplify this new paradigm, combining multi-technology capability, scalability, and digital integration to accelerate vaccine and biologics launches while maintaining quality and responsiveness.

#### **HIPRA SPEEDCELL: Accelerating Protein-Based Platform Vaccines:**

**Challenges:** HIPRA stated that recombinant protein-based vaccines are safe and effective but traditionally slow to develop. Accelerating cell-based vaccine manufacturing is critical to strengthen Europe's preparedness for health emergencies and align with CEPI's 100 Days Mission goal for rapid vaccine deployment.

**SPEEDCELL Project:** Funded by the European Union, SPEEDCELL aims to cut development timelines from over 28 weeks to under 100 days by optimizing cell line development and manufacturing workflows. It integrates new and proprietary technologies to improve gene synthesis, clone selection, and cell banking efficiency to address medicine shortages and supply chain vulnerabilities **(8)**.

**Flexible Manufacturing:** The project emphasizes modular, scalable, and single-use technology (SUT)-based facilities that enable quick capacity expansion. Flexible design, automation, and robotics enhance efficiency and reduce contamination risks, while maintaining readiness for increased production demands.

**Strategic Impact:** By combining digitalization, smart factory design, and robust supply chain management, HIPRA's model aims to advance Europe's manufacturing independence and competitiveness in biologics. HIPRA reported that SPEEDCELL represents a major step toward faster, adaptive vaccine production and greater health system resilience.

**Groups Discussions:** After the presentations and open discussions, the workshop participants were divided into breakout groups to discuss current & future vaccine innovation ecosystem with the concrete focus on what works well (baseline), what do we need to work on (goals) and which instruments or next steps are needed to achieve the goals.

**Conclusions and Recommendations:** The workshop highlighted that innovation is the cornerstone of a resilient and future-ready vaccine ecosystem. Industry reported that integrating platform knowledge and technologies, model-based development, use of digital tools such as AI and ML, and early regulatory engagement were highlighted as key strategies to accelerate vaccine product and process design and optimize manufacturing. Additionally, early engagement between academia, regulators, and industry was identified as essential to translating scientific advances into scalable, high-quality vaccine products.

Flexible, modular, and digitalized production facilities demonstrate how innovation can shorten vaccine production lead timelines, enhance adaptability, and support Europe's preparedness goals. Establishing flexible and harmonised regulatory frameworks, including but not limited to ICH initiatives, and robust data infrastructures will facilitate the safe and widespread adoption of these novel approaches. The workshop reinforced that innovation must be embedded across the entire vaccine lifecycle, considering preclinical, clinical, CMC development, and commercial manufacturing to ensure faster, more efficient, and equitable access to vaccines worldwide.

#### **Recommendations:**

- **Embed Innovation Early:** Integrate model-based, data-driven platform knowledge and technologies from the earliest stages of vaccine development to generate appropriate data to accelerate timelines and improve adaptability.
- **Advance Digital Transformation:** Expand the use of AI and modeling to enhance product and process understanding, predictive control, and manufacturing efficiency, ultimately supported by harmonised regulatory guidance.

- Stakeholders should test and explore modeling formats for clinical & CMC to create a link between both (e.g., dose finding studies). Potentially consider development of an EMA guidance on clinical modeling/design impact on CMC, e.g., for specification setting strategy.
  - The additional research on the use of AI and modeling strategies should optimally be in a global format, not regional.
- **Establish Data and Model Framework:** Develop shared digital infrastructure to enable interoperability, meaningful transparency, and deliver trust in AI- and model-based vaccine innovation.
    - It was highlighted that having a library to track different models and examples could be useful and beneficial for all stakeholders. The focus should be not only on successful cases but also include examples of product failure and pitfalls.
  - **Build Flexible Manufacturing Networks:** Invest in modular, multi-technology facilities that enable rapid scale-up, multi-platform capability, and resilient supply chains adaptable to health emergencies.
  - **Foster Public Confidence:** Support coordinated communication strategies that promote transparency around innovation, ensuring public understanding and trust in next-generation vaccine technologies.
  - **Promote Regulatory-Academia-Industry Dialogue:** Strengthen structured, continuous exchanges between regulators, academia and industry to ensure awareness from both sides and effectively translate emerging technologies into regulatory practice (e.g., Scientific Advice Working Party, EMA Emergency Task Force, EMA stakeholder meetings such as Quality Innovation Group (QIG) and Industry Standing Group (ISG)).

In conclusion, these recommendations underline the need for coherent frameworks, targeted investment in enabling technologies, and enhanced regulatory convergence to accelerate vaccine innovation. Strengthening collaboration among regulators, industry, and academia will be essential to ensure that digital tools, AI-driven processes, and modular manufacturing models are effectively integrated across the vaccine lifecycle.

Looking ahead, sustained commitment to harmonisation and science-based policymaking, as per ongoing EU legislative proposals, will be vital to embed innovation as a central pillar of Europe's vaccine strategy. Continued joint action between all stakeholders will help

translate technological progress into resilient, efficient, and globally competitive vaccine development and manufacturing systems.

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