# Transparent, Pret-a-porter Operations Quality Measurement & Other 2024 Priorities for Drug Manufacturers & the Supply Chain

In Life Sciences manufacturing quality and compliance, the global digitalisation drive continues a-pace as the pressure builds to innovate, collaborate and contain costs. REPHINE's Dr. Eduard Cayón rounds up the latest trends and challenges facing drug makers and their supply chain partners.

2023 has been a demanding year for Life Sciences manufacturing, with continued pressure to innovate, bring costs down and overcome very real global supply chain disruption through improved visibility and contingency planning.

The most significant and serious pharma R&D projects are concentrated in the biotech space now. Although small-molecule developments are still a focus of investment, this once dominant field is becoming steadily less strategically important. As a natural consequence, increased technology use has become a priority – both to support designated innovation, and to help deliver this efficiently and safely. Efforts to digitise and automate manufacturing operations and processes in smarter ways have seen a sharp acceleration in initiatives over the last year, coupled with a renewed commitment to tech-based process monitoring and improvement – among operations of all sizes.

Agility, flexibility, and robust transparency in front of regulators are among the reasons drug producers are upping their game technologically. All market players realise now that targeted technology use offers not only a way to expedite product delivery and contain risk and cost; but also connect in more fluid and traceable ways with other entities – from regulators, to supply chain partners, to clinical trial participants and sponsors.

Tools are much more accessible and affordable now, certainly. As a result, digitalisation of manufacturing operations and associated quality control has become a competitive imperative. That's as manufacturers across the world, from India and China, to the Middle East and South America become more technologically advanced, and at an accelerating pace. Even active ingredient (API) producers are investing in automation of operations monitoring processes that were previously managed manually.

Digital tool use isn't just for manufacturing operations oversight or laboratory quality control processes either, but also overall Quality management. Changes to everyday working practices during pandemic lockdowns, and extended remote working, have added impetus for Quality-related process change. Hybrid working and remote collaboration are now seen as an enduring model – supported by the cloud as a secure hub for sharing and exchanging information, across global operations and along the supply chain. That's as the benefits have been felt in process efficiency, and in overall transparency.

Feeding into these already established digital capability priorities, we have seen the growing need for:

**Accelerated Adaptability**
The pandemic underscored the significance of being adaptable and swiftly shifting production, research and development, not least because of the need to respond promptly to new viral or bacterial threats in the future. All of this demands that operations are comprehensively and reliably monitorable, and that relationships along the supply chain are strong but fluid, underpinned by a continuous, consistent information flow.

**Global Collaboration**
The development of treatments and vaccines for COVID-19 benefited from an unprecedented collaboration among governments, organisations, and corporations, setting a new precedent for addressing other diseases in the future. Ensuring that the lines of communication are open, standardised and tamperproof will be essential in fostering more spontaneous and timely exchanges, eliminating process bottlenecks.

**Supply Chain Innovation**
Disruptions in supply chains due to the pandemic have prompted companies to diversify their suppliers and consider local or regional production. This has an impact on supplier quality control and compliance monitoring, with implications for audits and ongoing reporting.

**mRNA Technologies**
mRNA-based vaccines proved efficacious against COVID-19, prompting the industry to explore further therapeutic applications for the technology. As manufacturers' ambitions grow, there are quality monitoring and control implications both for new production lines and international supply partnerships.

**Telemedicine & Digitalisation**
The integration of telemedicine with pharmaceutical services has the potential to revolutionize drug delivery and monitoring, making it more precise and tailored to individual patient profiles. Such integration could include digital tracking of medication adherence; remote consultation for prescription adjustments; and even the use of AI-driven analytics for predicting patient responses to certain medications.

**Regulation & Expedited Approvals**
The speed with which COVID-19 vaccines were developed and approved has spurred discussions about streamlining regulatory approvals in emergency scenarios without compromising safety.

**Ethics & Equity**
Ensuring equitable access to essential medications and treatments is likely to remain a salient concern, in the wake of discussions

around global access to COVID-19 vaccines. Ethical considerations play a vital role in healthcare policy and decision making. This is essential to balance the interests of the various stakeholders, including patients, healthcare providers, pharmaceutical companies, and government bodies. This balance is crucial in biopharma research and development, where the allocation of resources and prioritization of medical needs must reflect a commitment to serving the global community, not just the most profitable markets.

**Digital Transformation Drives**

As the whole Life Sciences industry strives to be more agile, responsive and competitive, the pressure is mounting for manufacturers to remove manual systems for process monitoring. As they digitise capabilities, companies must be able to provide system validation and evidence of secure traceability; so vouching that generated reports have not been tampered with or faked.

For manufacturers themselves, smarter operations and supply chain monitoring presents an opportunity to reduce the cost of production and its management, especially for conventional products whose prices are steadily declining.

**Trends Evolving in 2024**

In 2024, we can expect many of the themes above to continue to develop and accelerate. That's in addition to other priorities that will emerge or gain momentum during the year, including:

**Increased Pressure on R&D to Innovate**

R&D organisations being under pressure to accelerate the pace of innovation, focusing on emerging technologies and personalised therapies. Even in the large generics markets like China, traditional drugs manufacturers are diversifying into biotech where the potential market is large and lucrative.

**Lateral Tie-ups Between Complementary Specialists**

Alliances between pharmaceutical companies and tech specialists will multiply and flourish, particularly in the digital health space. Success will depend on the ability of those respective parties to communicate with each other on the same level, which includes their ability to standardise and streamline quality measures so that these are consistent and meaningful to both parties.

**A Growing Focus on Unmet Clinical Needs**

The growing focus on unmet clinical needs, targeting previously neglected diseases and rare conditions, is driven by advances in personalized medicine, innovative partnerships, regulatory incentives, and increased patient advocacy. These efforts represent a shift towards more inclusive and responsible healthcare, emphasizing the need for broader access and treatment options across various health conditions.

**A More Active Effort Towards Net Zero**

Finally, and importantly, the pharmaceutical industry is deepening its commitment to sustainability and to achieving Net Zero. Specific drives in 2024 are likely to include:

1. Energy efficiency improvements: e.g. to adoption of renewable energy and more efficient manufacturing processes;
2. Adoption of eco-friendly packaging;
3. Green chemistry: the growing implementation of environmentally-friendly practices in drug production;
4. Waste management: proper disposal of pharmaceutical waste to prevent a negative environmental impact; and
5. Sustainable supply chains: more ethical sourcing and responsible material procurement.

Together, such initiatives reflect the industry's commitment to environmental responsibility, aligning with global sustainability goals.


## Dr. Eduard Cayón

Dr. Eduard Cayón is Chief Scientific Officer at REPHINE, which provides bespoke technology and manufacturing supply chain compliance consultancy and third party auditing. REPHINE offers services all around the world from four primary locations – Stevenage in the UK, Barcelona in Spain, Hyderabad in India and Shanghai in China. Dr. Cayón, who holds a Ph.D. in Organic Chemistry, is a deeply experienced pharmaceutical industry consultant and auditor.