

Creating a MANUFACTURING INTELLIGENCE PLATFORM with zenon

Meribel Pharma Parets digitalizes batch records

[Meribel Pharma Solutions](#) is a contract development and manufacturing organization (CDMO), providing drug development and pharmaceutical manufacturing services to pharmaceutical and biotech companies. Prioritizing innovation, the highest quality standards, employee experience, and talent attraction, Meribel recently launched a digitalization program at its Parets manufacturing location in Spain. System integrator [Appliant](#), a COPA-DATA Gold Partner, deployed the zenon software platform to digitalize Meribel's batch records, improve quality, and simplify compliance reporting.



CHOOSING ZENON TO DIGITALIZE BATCH RECORDS

Founded in 2024, Meribel has 11 sites across the EU, including both drug development sites and manufacturing facilities spread across France, Spain, and Sweden. Meribel's Parets site, just outside Barcelona, offers multi-functional pharmaceutical manufacturing capabilities within an 11,900 m² footprint. As well as supporting a wide range of dosage forms, including solids, semi-solids, and non-sterile liquids, it offers advanced solutions for specialized packaging. The site is also certified to manufacture clinical trial and veterinary products. It holds cGMP, ISO 13485, ISO 14001, and ISO 45001 certifications, underwriting its reliable, compliant production.

The CDMO is committed to ensure the safety of the medicines it produces for its customers, with rigorous quality assurance measures and unwavering adherence to GMP standards, ensuring products are manufactured with the utmost care and precision. Until recently, the collection of shopfloor batch data and the release of batch records at Parets had relied on manual systems. This meant a batch release process could take up to eleven days.

Meribel wanted to improve these manual processes, making them more accurate, more reliable, and faster through digitalization. Teia Forcat, Operations Director at Meribel Parets, explains, "We want our digital transformation to improve the



The eBR has embedded a Review & Approval process for batch release according its authorization workflow and connected to the Active Directory.

accessibility of data, reporting, and continuous improvement. We also know that, by taking a lead on digitalization and innovation, we can attract and retain the best talent, especially new talent from younger generations.”

MERIBEL PRIORITIZES DIGITALIZATION AND INNOVATION

Meribel opted to work with Barcelona-based Appliant, a system integrator that specializes in empowering customers through the digitalization of production processes and plants. Its manufacturing intelligence platform (MIP) for the pharmaceutical industry is based on the zenon software platform from Austrian industrial automation software company, COPA-DATA.

Meribel’s digitalization initiatives at the Parets location were hindered by heterogeneous machinery on the shopfloor, isolated data silos, and manual data collection processes. In particular, the batch records involved a lot of manual work. Each manufacturing room had its own documentation and procedures. This was non- efficient and entailed a strong reliance on manual processes. Additionally, the lack of available process data reduced the team’s capacity to perform root cause analysis of any deviation or corrective actions preventive actions (CAPA) execution.

“We needed one simple platform for all our data that didn’t rely on paper so we could gain real-time visibility of our operations and ensure data integrity and compliance everywhere,” says Teia Forcat. “We chose zenon to give us this platform.”



The MIP provides Meribel with real-time information of any process step in any cleanroom – from anywhere.

APPLIANT RECOMMENDS ZENON FOR “PAPER ON GLASS” SOLUTION

Appliant began by working with Meribel’s quality and manufacturing teams to create a digital, tablet-based solution that could replace the slow, manual, paper-based processes. The input of the final users in shaping zenon’s graphical user interface was an important success factor.

“zenon is the perfect solution here because it offers enough flexibility to adapt the Paper-on-Glass (PoG) tool to daily operations, smoothing the transition to a digital solution with a similar look and feel to the paper-based standard operating processes,” explains Marc Ramoneda, CEO at Appliant.

To create the solution for Meribel, Appliant leveraged zenon’s PoG, Recipe Group Manager, Historian, Reports, Message Control and Extended Trend modules. These native capabilities, when paired with zenon’s unparalleled connectivity with shopfloor systems, meant the solution could be delivered quickly and with minimal engineering effort. Customizations were possible, using zenon’s integrated Logic and support for Add-Ins, but kept to a minimum thanks to zenon’s wide-ranging, sector-specific capabilities and the expertise of the Appliant team.

Marc Ramoneda explains, “Using zenon enables us to reduce engineering efforts and validation resource. For example, the GAMP 5 Category 4 compatibility of zenon reduces the validation workload, as the integrator handles much of the configuration and testing – allowing for a faster, more streamlined implementation.”



Different people can interact simultaneously from different devices, including using the eSignature capability, and all actions are recorded and can be tracked in the Audit Trail

DATA INTEGRITY AND MANUFACTURING OPTIMIZATION IS IMPROVED

The PoG batch records solution and new digital standard operating procedures (SOPs) have improved data integrity and connect data from across the site. Live monitoring of all processes is now possible. As well as reducing administrative effort, real-time monitoring helps the quality team to reduce waste.

Alba Nieto Conde, Production Compliance Officer at Meribel Paretis, explains, “The new system makes our lives easier and reduces mistakes because each step is verified in real time. Furthermore, mistakes in batch records are trending to zero. The time we previously spent on revisions can now be redirected to more value-adding work.”

If problems are found, they can be investigated quickly. Even six months after the fact, root cause analysis will present no problem to be addressed quickly. Operators, the quality team, and management now enjoy robust and rapid access to all relevant production data, thereby enhancing efficiency and transparency and making continuous improvement initiatives possible.

“zenon’s scalability, adaptability, and connection to pre-existing systems make it easy for us to integrate different solutions – including supervisory control and data acquisition (SCADA), overall equipment effectiveness (OEE) and consumption – in the same MIP,” asserts Marc Ramoneda.



Real time visibility of the status of current batches, scheduled batches, and previous batches.

“Meribel can scale up different SOPs as needed. Having the data centralized in one system also gives the Meribel team new opportunities to exploit the data for different objectives.”

IMPROVING THE SERVICE TO CUSTOMERS

Digitalization has enabled the Meribel Partes team to automate essential reporting requirements, such as standard deviation reports. The new electronic batch record (eBR) has replaced the old paper-based processes and eliminated related errors, such as missing entries or signatures.

Meribel can now review by exception using the eBR and, as a result, the batch release time has been reduced from eleven days to just two to three days. As well as improving efficiency for Meribel, these time savings make it possible for Meribel’s customers to reduce their time to market.

In the longer term, now that data is accessible to everyone in the company with the right permissions, the quality of operational reports and annual product quality reports (PQRs) will improve. These reports will now be generated automatically, delivering further time savings and quality improvements for the Meribel team.

“zenon’s native validated package makes it easy to implement the solution in pharmaceutical companies. With zenon, you can start small – and aim big!”

- TEIA FORCAT, MERIBEL PHARMA PARETS
OPERATIONS DIRECTOR

CONTINUING DIGITALIZATION PROGRESS

“I would recommend zenon for many reasons,” says Teia Forcat. “Because it is a modular solution you can get started with it quickly and take an evolutionary, rather than a revolutionary, approach to rolling it out across the factory. zenon is easily acceptable to all teams and cost-efficient.”

“COPA-DATA and Appliant have delivered a high-value service, accompanying us throughout the transformation process. Most importantly, zenon’s native validated package (21 CFR Part 11 and GMP Annex 11 and more) makes it easy to implement the solution in pharmaceutical companies. With zenon, you can start small – and aim big!”

The company plans to continue to develop the solution. In the future, an increasing number of values will be retrieved directly from the machine or sensor, so that the operator does not need to enter values manually. Meribel will also use zenon to compare manufactured product against the ideal, making real-time rejections possible.

Connection with HR systems to ensure operators have the right skills and training to operate a particular machine is another innovation under consideration. The team also plans to include OEE tracking system into the platform.

Teia Forcat concludes, “I am obsessed with the future – and paper is not the future! We are now ready for what comes; we can attract and retain the best talent and all our people can be proud to work here.”

HIGHLIGHTS:

- ▶ A GMP Validated Manufacturing Intelligence Platform
- ▶ Tailored “Paper on Glass” solution replicates existing paper-based standard operating processes (SOPs)
- ▶ Time efficiencies with automated data capture, delivering real-time visibility of manufacturing operations
- ▶ Electronic batch records (eBR)
- ▶ eBR ensures zero missing entries
- ▶ eBR with 100% process fulfillment
- ▶ Review by exception
- ▶ Faster time to market: batch release process down from 11 days to 2 days
- ▶ More accurate, automated reporting