

Reports that matter: BioMarin uses the PI System™ to build better batch review

INDUSTRY

PHARMA &
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CHALLENGE

Batch reports delivered large amounts of irrelevant data, requiring lengthy manual review and slowing down product release process.

SOLUTION

Use the PI System to build batch-centric reports, which are tailored to deliver critical parameters for each batch.

BENEFIT

New reports simplify the quality assurance process and reduce number of delays in product delivery.

BioMarin's legacy system for creating batch reports worked – just a little too slowly. The extensive manual review required to do quality assurance for each batch was bogging down the process of getting products to market. Faced with a bottleneck in the manufacturing process, BioMarin engineers wondered, could they use the PI System to create more streamlined, tailored reports, and deliver only the information that mattered?

BioMarin, headquartered in San Rafael, California, is a specialized pharmaceutical company that focuses on developing therapeutics for patients with very rare genetic diseases. The company has seven approved drugs on the market, some of which are the first or only medications targeted to the rare disorders they are designed to treat. The company is growing and making better use of data is key to that expansion.

“As we've grown, we've faced a larger and larger need to shore up our manufacturing practices as well as our business practices,” said Travis Pereira, a data systems engineer at BioMarin.

Watching the detectives

BioMarin has an Enterprise Agreement with OSIsoft. Since 2012, the company has used the PI System to track manufacturing data at plants in Novato, California, and Shanbally, Ireland. The company relies on the PI System to serve as a single source of truth across the enterprise. The PI System collects and organizes key data that BioMarin needs to ensure product quality and meet high regulatory standards.

More recently, BioMarin has been using the PI System to generate reports that the quality assurance (QA) group uses to review batches for release. Initially, these reports delivered plenty of data, but not necessarily the right data. Reports were oriented towards individual pieces of equipment and manufacturing processes, not drug batches. The reports included a lot of information that wasn't relevant to the QA process, which increased review times. Because the reports did not present the information the QA team needed in a clear and obvious way, engineers sometimes had to conduct

extensive manual reviews of certain production processes to verify the information.

“The result was that the QA group ended up doing a lot of detective work,” Pereira said. The manual reviews worked because the QA engineers have a wealth of experience and are well-versed in the quirks of the manufacturing process. But relying on engineer knowledge wasn't a sustainable or scalable solution. BioMarin needed a better way.

Beyond the data dump

To build better reports, BioMarin needed to embrace the idea that not all parameters matter equally. Quality assurance engineers needed reports focused on parameters that were critical to batch quality, had robust online measurements, and could trigger alarms if certain values fell outside the defined acceptable range.

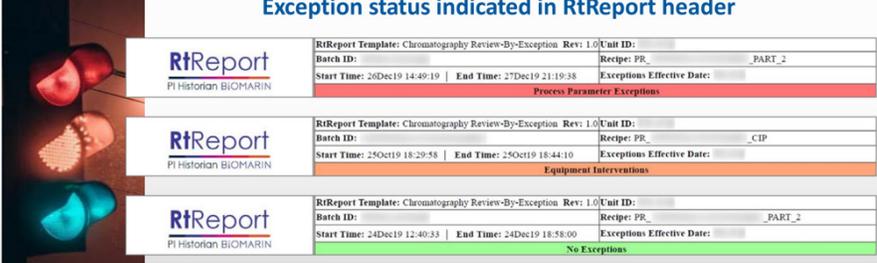
BioMarin used PI System tools to build a new reporting process that centered on the principle of review-by-exception.

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The end goal:
Decrease
batch review
times and
bring our
products
to patients
faster.”

— Nick Monteleone,
Data Systems Engineer
BioMarin

Path Forward: Review-by-Exception RtReports



Templated RBE RtReports

Exception status indicated in RtReport header

RtReport Template: Chromatography Review-By-Exception Rev: 1.0	Unit ID:
Batch ID: [REDACTED]	Recipe: PR, [REDACTED] PART_2
Start Time: 26Dec19 14:49:19 End Time: 27Dec19 21:19:38	Exceptions Effective Date: [REDACTED]
Process Parameter Exceptions	

RtReport Template: Chromatography Review-By-Exception Rev: 1.0	Unit ID:
Batch ID: [REDACTED]	Recipe: PR, [REDACTED] CIP
Start Time: 25Oct19 18:29:58 End Time: 25Oct19 18:44:10	Exceptions Effective Date: [REDACTED]
Equipment Interventions	

RtReport Template: Chromatography Review-By-Exception Rev: 1.0	Unit ID:
Batch ID: [REDACTED]	Recipe: PR, [REDACTED] PART_2
Start Time: 24Dec19 12:40:33 End Time: 24Dec19 18:58:00	Exceptions Effective Date: [REDACTED]
No Exceptions	

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BioMarin’s streamlined, batch-centric reports are designed on the principle of review by exception, providing quality assurance engineers with a clear status for each critical parameter.

First, engineers went through the list of parameters in the legacy reports and assigned a review strategy to each critical quality parameter. Those parameters that met all the criteria for review-by-exception were selected for inclusion in new, streamlined RtReports. The RtReports now present simple, binary classifiers to flag any exceptions to acceptable parameters.

While taking stock of each to see if it should be included in the review-by-exception reports, BioMarin engineers found several cases where parameter alarms had not been set at all or were set outside of the proper acceptable range for a given parameter. Fixing these issues has cut down on the amount of time that operators spend on manual reviews.

The PI System plays a crucial role in creating the new reports. BioMarin uses Event Frames to create templates for each equipment type. These templates build on the ‘digital twin’ of the company’s assets in Asset Framework, the contextualization

layer of the PI System. As BioMarin adds new equipment, these templates make it easy to add the new assets to the reports. BioMarin has also partnered with Lucid Automation and Security for automation work and with Spiritech Solutions for reporting implementation.

“This is a bit of a culture shift for our company, being that we were used to reviewing those alarm limits and doing the manual trends, but all in all, we had the organizational buy-in and support to revamp these alarm strategies and then deploy the simplified approach,” said Nick Monteleone, an automation applications engineer at BioMarin. “Going forward, we will have a much more straightforward online measurement review process.”

For more information about BioMarin and the PI System, watch the full presentation [here](#).

Monteleone, Nick and Pereira, Travis. “Finding What Matters — Implementing Review-by-Exception RtReports for Manufacturing at BioMarin.”