INNOVELOCITY

Biotechnology firm achieves ISO/MDSAP certification and over 90% improvement in data analysis/reporting efficiency

Summary

1. **Audited and documented all key processes, ensuring compliance with ISO/MDSAP certification requirements.**
2. **Automated Quality Control processes, driving transformational improvements in lead time, quality and efficiency.**
3. **Delivered project with high efficiency: small 2.5 person project team and no additional headcount at the customer.**

Background

Biocare Medical offers a portfolio of integrated products to address cancer and infectious disease diagnostic and research markets, including immunohistochemistry instrumentation and the full range of reagents for IHC lab testing.

With a transition to new ownership in 2017, the new management team at Biocare Medical needed to quickly understand the overall business and define a roadmap for the company's growth and success.

InnoVelocity was selected to audit and document Biocare Medical's key operational business processes-in order to align the organization on current practices, and to identify opportunities for improvement. This documentation was especially important as Biocare Medical was preparing for Medical Device Single Audit Program (MDSAP) certification in 2019.

"This project was instrumental for BioCare's growth and success for two key reasons: one, critical business knowledge was transferred into repeatable business logic, and two, the time to train and ramp up additional new resources was greatly reduced."

Morgan Porter, Biocare Chief Operations Officer

Solution

PHASE 1: AUDIT AND DOCUMENTATION

An expert InnoVelocity auditor/consultant led the process to quickly document 21 core processes:

Instrument Production	Supplier Management	Internal Audit
Instrument Design & Development	Customer Complaint Handling	CAPA Process
Instrument Installation	Marketing Content Development	Recall Process
Instrument Relocation	Recruiting/Hiring	Medical Device Reporting – Recall Process
Reagent Production	Data Management	Reagent Quality Control
Reagent Design & Development	Regulatory Planning	Change Control
Shipping/Receiving	Training	Supplier Material Selection/Qualification

This documentation was published to an interactive online portal that any employee could access – and it was used successfully to align the organization on a common set of operating methods and procedures, was instrumental in Biocare achieving their audit certification.

PHASE 2: DIGITAL PROCESS AUTOMATION

After full evaluation of these processes, Biocare Medical determined that optimization of the Quality Control process would have the most significant impact, and would be the first candidate for Digital Process Automation (DPA) – with the following gains expected:

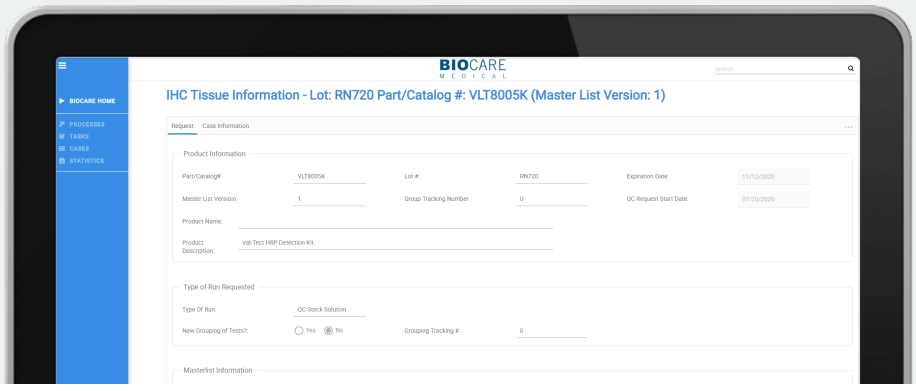
- Ensure that the processes are appropriately designed and modeled for efficiency and compliance, with best practices and ISO requirements built in.
- Institutionalize these processes through automation - ensuring they are followed consistently, with a full audit trail to match.
- Provide efficiency improvements by automating previously manual work tasks.
- Accelerate throughput time by providing visibility, reminders and other tools to keep work moving.

The primary focus was on digitizing error-prone paper forms and manual workflow, but additional systems of record would also be established for the Reagent master list and the equipment and materials lists, to vastly increase data quality and consistency.

Based on Biocare Medical's key requirement for flexibility, configurability and low total cost of ownership, AXON Ivy was selected as the preferred DPA vendor, per InnoVelocity's recommendation.

The first deployment of the Reagent QC process was in Q1 of 2020 and to date, the solution has provided strong gains with regard to customer lead time, number of quality issues and efficiency. The feedback from Biocare Medical has been excellent and they have plans to expand the Axon.ivy Digital Business Platform to other areas of their business.

	Time Spent Pre-Implementation	Time Spent Post-Implementation
QC Test record verification	33 hours/month	0 hours/month
QC Key Performance report	16 hours/month	4 hours/month
Total	49 hours/month	4 hours/month



"We recommended the Axon.Ivy Digital Business Platform to Biocare because of its incredible flexibility, stability, and value proposition. Our developers are able to quickly deliver applications with tailored user experiences and incredible reliability, in a way that many other 'low code' platforms can't match."

Neil Simpson, InnoVelocity CEO/Principal

INNOVELOCITY

InnoVelocity Inc is a leading systems integrator and management consulting firm specializing in Digital Process Automation (DPA) technologies including Axon Ivy, Bizagi, K2, UIPath and Tableau. InnoVelocity has a 13+ year track record helping industry leaders in healthcare, finance, manufacturing and government achieve outstanding business results.
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BIOCARE MEDICAL

Biocare Medical, LLC is an innovator in developing and supplying world class automated immunohistochemistry instrumentation, and the full range of reagents for IHC lab testing. Biocare is the market leader in simultaneous multiplex IHC tests which provide increased confidence at critical diagnostic decision points, impacting patient therapy while accelerating turnaround time.