Lab and production services

Success story

Avantor accelerates Cell and Gene Therapy (C&GT) production

CHALLENGE

A global pharmaceutical company set an ambitious strategic goal of transitioning from Cell and Gene Therapy (C&GT) concept to full-scale GMP production within a year. Despite the customer's global recognition in personalized medicine, this was a new segment of production requiring significantly different skills and processes. The current-state processes provided room for optimization. To scale up production processes, the critical environment and process controls needed to be specified. This included specification of: critical materials requirements, PPE and consumables needs, production support and logistics processes, and staffing levels required by functional area.

Our customer was entering a challenging new production space under stretch timelines with little to no organizational infrastructure to support. We provided the subject matter expertise, project oversight and continued services support to exceed customer goals and leave ongoing services solutions in place that adapt to our customers changing needs.

SOLUTION

Avantor recognized the challenge our customer was facing moving from a white space to full scale GMP C&GT production in less than a year. We formed a cross-functional team to guide our customer through the design-stage projects and production process commissioning.

Led by Avantor's Process Consultants, we brought together six business functions offering their unique expertise to ensure our customer established an efficient production work environment and processes with the right materials, controls and data. Key contributions by each area of our business are illustrated in the table.

Additional support provided by our expanded global Avantor team complemented the four production services segments of Design Stage Consulting, Planning & Material Management, Production Readiness, and Critical Environment and Sanitization. Each of these services categories delivers specific tasks and activities outlined below.

Innovation leadership	Strategic direction
	Global benchmarks
	Best practice comunication
Avantor site services	Design stage consulting
	Lean Six Sigma Master Black Belts
	Project management
	Digital integration
Product sales	Production C&GT consumable and bill of material identification
	Furniture and equipment expertise
	Critical environment expertise
Biorespository	Production quality retain standards
	Global cryo-shipping protocols
	Chain of custody
Critical environment	Environmental monitoring
	Gowning guidelines
	Santitization protocols
Single-use	Streamlined component assemblies
	Production kitting
	Sterilization

Planning and material management	Consulting Services	Critical Environment & Sanitization	Production Process Readiness
– cGMP material sourcing, QC and warehousing – Validated digital solutions with customer platform integration – Chain of custody and document management – Integrated forecasting and production planning – Vending solutions – Chemical management	– Design stage production consulting services – Process DFSS – Commissioning project management – Protocol and standard work development – Production method and workflow optimization	– Production space and process equipment sanitization – Environment monitoring protocol development, testing & monitoring – Excursion investigation, response and recovery – Test equipment certification and management – Control and monitoring of aseptic processing cleanrooms	– Equipment and instrumentation stewardship and technical services – Process support, staging and kitting – Material sampling, testing and release management – Validation and quality testing – Clinical receiving and registration – Protocol driven workflows

RESULTS

In this project, Avantor set our Customer Clinical GMP C&GT Production and Science in motion. We exceeded our customer timelines by an estimated one month and built efficient low-cost processes to meet production goals of 12 patients per month.

Leveraging our C&GT expertise, our customer saved three months building their team and eliminated staffing risks associated with acquiring permanent resources before processes and work function requirements were defined. Overall this saved our customer time and costs, allowing them to make better staffing and talent acquisition decisions as internal demands grew.

Lean process design was utilized to minimize steps in material logistics and quality processes, and reduce staffing needed by an estimated 5 employees. Additionally, these processes leveraged several digital integration points and reporting capabilities.

To further mitigate risks and ensure process continuity, a form-based manual process was developed. This process was leveraged to go live with production on time as some of the customer's digital systems were not operational to support their ambitious timeline.

Biopharma, consumable and critical environment product specialists provided turnkey product lists and lean stocking levels supporting our customer's consumables and manufacturing Bill of Materials. Our single-use team consulted on 47 lower cost sterilized assemblies, projected to save millions of dollars annually while eliminating patient risks. Lean material stocking levels and controlled pre-production kitting/staging and material sterilization were built into sustainable processes to reduce costs from the first production runs.

Finally, our team of four services associates were deployed to execute on the Material Ordering, Material Issuance, Sample Logistics, Production Support Services and other ancillary tasks. Each of these services delivered is performed under the controlled SOP developed by Avantor. An overview of these services is provided below.

Material ordering	Incoming materials handling	Materials issuance	Sample logistics	Supporting services	Additional documentation
– Forecast stocking adjustment – GMP Inventory Monitoring – Non-GMP Inventory Monitoring – Purchasing – Purchase order processing – Receipt date updating	– ERP receiving – Spec review and inspection – Purchasing system receiving – Detrash and quarantine – Release labelling – Wipe down in GMP receiving – GMP materials storage – Non-GMP materials storage – Rejected materials management	– Picking and issuance – Kitting – Wipe down in grade D to C transition – Gowning into kitting – Wipe down into kitting – Material transfer to workstations – Kitted materials request handling	– Incoming materials sampling – Sample label printing – Sample transfer to QC – In process sample pulling – Finished product sampling – Test environmental monitoring sample logistics – Periodic environmental monitoring sample logistics – Environmental monitoring sample transfer to environmental monitoring micro lab	– Bio-waste staging – Waste packing and transfer – Disposable gowning collection – Reusable gowning collection – Shipping dewar and dry ice – Package document preparation – Finished product shipping – Patient material handling	– Room & workstation cleaning – Cleanroom gowning into grade D – Cleanroom gowning into grade C – Cleanroom gowning into grade B – Spill containment – Cycle counting

Avantor Services

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