VALSOURCE

GMP Consulting for ATMPs

001. Why ValSource for GMP Consulting for Advanced Therapy Medicinal Products (ATMPs)?

ValSource consultants have unparalleled expertise to help navigate the complex regulatory environment of ATMPs. We provide full services for key challenges including employing a science driven, risk-based approach to ensure success. Our consultants are widely known as thought leaders on ATMP development and manufacturing.

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An Emerging Field

- Advanced therapy medicinal products (ATMPs) are innovative therapies that encompass gene therapy, cellular therapy, and tissue-engineered products.
- The development of ATMPs is a dynamic and fast-growing field of interest.
- Although most of the products are in an early development phase, the combined trial phase and the potential to cure severe chronic conditions suggest that ATMPs may reach the market earlier than standard therapies.
- In just the past few years, there have been many approvals of ATMPs by global regulatory agencies. Hundreds of these therapies are now rapidly moving through clinical development, which presents unique challenges to the development and manufacture of these products.

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Industry Experts

- ValSource consultants are the industry's leading experts on ATMP development, manufacturing, quality and compliance.
- While other consultants may know the standards, ValSource consultants write them. Our consultants have worked along side regulators to author guidance documents, technical reports, white papers, and standards.
- Our consultants have extensive experience through all stages of product lifecycle with both established companies and startups.

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SPECIALITY CONSULTING

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Ways We Can Help

- **Facility:**
  - Facility and equipment procurement and design consultation
  - Commissioning, Qualification, and Validation of Facility, Utilities, Equipment, and GMP systems
  - Calibration & Metrology and Preventive Maintenance services
  - CDMO vetting and selection
  - Site Specific Safety Plan (SSSP)

- **Support Systems:**
  - Quality system development and improvement for phase-appropriate GMPs
  - Quality Risk Management program development and risk assessment facilitation
  - Regulatory filing strategies and authoring
  - Contamination and cross contamination control strategy development and remediation support
  - Aseptic processing expertise and sterility assurance
  - Audit and inspection readiness and observation response

- **Process:**
  - Process validation lifecycle (design, qualification, and continued process verification)
  - Control Strategy establishment including process characterization, optimization, scale-up, and troubleshooting
  - Comparability studies and change management
  - Technology transfer and knowledge management
  - Capacity planning studies and demand readiness
  - Raw and starting material selection, risk assessment, and qualification
  - Risk-based sample plan development
  - Stability program design and execution

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About ValSource

- Since 1996, ValSource has worked with hundreds of pharma, biopharma, and medical device organizations around the world.

- Our 350-strong talent force has proudly served our clients as advisors, trusted consultants, and highly experienced program managers.

- We offer a complete line of services to ensure client projects speed-to-market and success.

- Our experienced staff is by your side – from start to finish.

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Learn More

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