VALSOURCE

Radiopharmaceutical Manufacturing Solutions



001. Why ValSource?

ValSource's team of experienced consultants provide risk-based solutions specifically tailored to radiopharmaceutical realities, supporting the unique GMP needs of radiopharmaceutical manufacturing.

002

Therapeutic Innovation Accelerated

Radiopharmaceutical manufacturing presents unique challenges that sit at the intersection of aseptic processing, accelerated timelines, radiation safety constraints, and evolving global GMP expectations.

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Industry Experts

- Our team combines expertise from traditional sterile pharmaceutical manufacturing with hands-on radiopharmaceutical experience to support practical, phase-appropriate solutions designed to be scientifically defensible and operationally realistic.
- Dedicated subject matter experts offer integrated expertise in sterile product manufacturing.
- We incorporate a practical understanding of accelerated manufacturing timelines and short product half-life constraints into support tailored to clinical phase, operational maturity, and regulatory expectations.
- 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 manufacturing support to ensure client projects speed-to-market and success.

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SPECIALITY CONSULTING

004

Ways We Can Help

FACILITY DESIGN & MANUFACTURING SUPPORT

- Phase-appropriate facility and cleanroom design support
- Aseptic processing workflows tailored for radiopharmaceutical operations
- Hot cell, isolator, and classified space integration strategies
- Material, personnel, and waste flow optimization
- Cleanroom zoning and HVAC risk considerations
- Design review for GMP readiness and operational practicality
- Process Performance Qualification (PPQ) strategy, protocols, and reports

COMMISSIONING, QUALIFICATION, & VALIDATION (CQV)

- Commissioning, Qualification, and Validation (CQV) strategy development
- Facility and equipment qualification support
- Smoke studies and airflow visualization
- Utility qualification (compressed gases, HVAC, clean utilities)

QUALITY RISK MANAGEMENT & DECISION SUPPORT

- Risk-based approaches aligned with ICH Q9(R1) principles
- Phase-appropriate risk assessments for radiopharmaceutical manufacturing
- Contamination control risk assessments aligned with US FDA and EU GMP Annex 1 expectations
- Facility, process, and workflow risk evaluations
- Environmental monitoring and microbial risk trending
- Intervention and aseptic process risk assessments
- Risk-based justification for monitoring, qualification, and control strategies
- Support for scientifically defensible decision-making under accelerated timelines
- Integration of QRM into deviation, CAPA, and change management systems

QUALITY SYSTEMS & GMP READINESS

- Development of scalable risk-based quality systems for early-phase through commercial manufacturing
- Gap assessments aligned with 21CFR211 and 212, US FDA, and EU GMP Annex 1 expectations
- SOP and batch record development and procedural harmonization
- Batch record and documentation review
- Inspection readiness support

STERILITY ASSURANCE & MICROBIOLOGY

- Phase-appropriate contamination control strategies (CCS)
- Environmental monitoring program design
- Risk-based microbiological control strategies
- Aseptic process risk assessments
- Investigation support for EM excursions and deviations
- Contamination control strategy development and training
- Environmental Monitoring Performance Qualification (EMPQ)
- Media fill / APS program development
- Cleaning validation and disinfectant qualification support

QUALITY CONTROL & LABORATORY SUPPORT

- QC microbiology laboratory design input
- Sampling strategy and testing workflows
- Stability, bioburden, sterility, and endotoxin program support
- Laboratory GMP readiness assessments

006

Learn More

ValSource.com

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