

# **Associate Aseptic Consultant - Job Reference #: 300520261**

## **Position Summary**

Aseptic Experts is seeking an experienced and motivated Associate Consultant – Aseptic Processing & Contamination Control to support and lead consulting, training, and compliance-related projects within pharmaceutical, biotechnology, compounding, and medical device environments.

This role is designed for professionals with strong technical experience in aseptic processing, contamination control, environmental monitoring, microbiology, sterile manufacturing, or quality operations who are looking to expand into consulting and operational leadership support.

The Associate Consultant will support contamination control initiatives, gap assessments, risk assessments, aseptic observations, training program implementation, technical documentation development, and operational readiness activities while working directly with client leadership and cross-functional teams.

## **Key Responsibilities:**

- Lead and support contamination control and aseptic consulting projects within regulated manufacturing environments
- Conduct facility walkthroughs, operational assessments, and gap analyses related to aseptic processing and contamination control systems
- Perform and support risk assessments, contamination investigations, and remediation activities
- Conduct aseptic observations and identify operational or behavioral contamination risks
- Support development and implementation of aseptic training programs and contamination control initiatives
- Develop and revise SOPs, technical reports, risk assessments, training materials, and compliance documentation
- Support environmental monitoring program assessments, trending reviews, and contamination control strategies
- Participate in client meetings, project planning activities, and technical discussions with cross-functional teams
- Support inspection readiness initiatives through documentation review, training support, and operational assessments

- Assist with mentoring and supporting junior consultants as assigned

**Minimum Qualifications:**

6–8 years of experience within one or more of the following areas:

- Aseptic Processing
- Environmental Monitoring
- Sterile Manufacturing
- Microbiology
- Cleanroom Operations
- Pharmaceutical or Biotechnology Manufacturing
- Quality Assurance or Quality Operations

**Strong working knowledge of:**

- Aseptic processing principles
- Contamination control strategies
- Environmental monitoring programs
- cGMP regulations
- Good Documentation Practices (GDP)
- Quality systems and compliance expectations

Experience participating in or leading:

- Gap assessments
- Risk assessments
- Investigations
- CAPA activities
- Training initiatives
- Compliance remediation efforts
- Strong technical writing, organizational, and communication skills

**Ability to independently draft:**

- Reports
- SOPs
- Risk assessments
- Observation summaries
- Technical documentation
- Training materials

- Proficiency with Microsoft Office applications including Word, Excel, PowerPoint, and Teams

### **Preferred Qualifications**

#### **Experience with:**

- EU GMP Annex 1
- USP <797> and <800>
- ISO 14644
- Environmental monitoring trending
- Aseptic observation programs
- Root cause investigations
- Data integrity initiatives
- Operational readiness programs

#### **Bachelor's degree in:**

- Microbiology
- Biology
- Chemistry
- Pharmaceutical Sciences
- Engineering
- Related scientific discipline
- Previous consulting or client-facing experience preferred

#### **Core Competencies:**

- Technical expertise
- Professional communication
- Leadership presence
- Technical writing
- Risk-based thinking
- Organizational skills
- Problem solving ability
- Client focused professionalism
- Team collaboration
- Continuous learning mindset

#### **Work Environment:**

- Combination of remote and on-site consulting activities
- Ability to travel based on client and project requirements

- Work within pharmaceutical, biotechnology, compounding, and controlled manufacturing environments requiring appropriate gowning and cleanroom practices
- Why Join Aseptic Experts?

Aseptic Experts is focused on building practical, sustainable contamination control and aseptic manufacturing solutions that improve operational performance and strengthen regulatory readiness.

Our consultants work directly with clients to support real-world operational improvements while continuing to develop technical expertise within highly regulated industries.

This role offers the opportunity to contribute to meaningful consulting initiatives while helping organizations strengthen contamination control, aseptic behaviors, and operational excellence.