Dr. Ashtekar is a results oriented collaborative and Industry recognized expert leader in **Pharmaceutical Microbiology, Sterility Assurance** and **Sterile product manufacturing** with over **33 years** of successful proven record of handling increasing responsibilities in leading Pharmaceuticals small molecule, Biotechnology (monoclonal antibodies), Biologically derived (microbial fermentation processes) protein therapeutics, Cell therapy, and plasma fractionation and plasma based products, Device and Vaccine industries. He is a member of **United States Pharmacopeia** (**USP) Council for Expert** **Microbiology Committee (2010-Current**). In addition, he serves as one of the **key experts** several **Parenteral Drug Association (PDA)** taskforces and authored several Technical Reports (Environmental Monitoring TR 13, Mycoplasma Clearance by Filtration and Rapid Microbiology Methods, TR 33). He also served as lead member on **International Society for Pharmaceutical Engineering (ISPE) Data Integrity** Task Force.

He has extensive experience with Sterility Assurance, Quality System, Quality Culture, Data Integrity and sterile Drug Manufacturing, Aseptic Processing, Aseptically Filled products and devices, Radiation and Terminally Sterilized products by moist heat.

**Awards and Honors**:

* Winner of AstraZenica-MedImmune Inc prestigious **Chairman Award for outstanding contributions and most valuable employee** award for the year 2002.
* Recipient of prestigious **Amgen Quality Excellence (2008) and Excellence in Operations Award (2009)** for the global standardization of Sterility Assurance and Microbiology systems.

**Patents**:

* Teva-GensiaSicor Pharmaceuticals**:** Sterile Propofol Metabisulfite®US 6147122, FDA approved); CIBA-GEIGY: Development of long Acting Rifamycin antibiotics (Patents U.S. 4, 681, 938; CH 221003131).

Dr. Ashtekar has held several leadership roles in large pharmaceutical and Biotech companies

1. Executive Director, **Intarcia Therapeutics, Hayward, CA**
2. Principal Consultant, **PAREXEL International** Waltham, MA
3. Sr. Director Quality Control, **Gilead Sciences**, San Dimas, CA
4. **Chief Microbiologist for Operations**, **Amgen Inc.,** Corporate Quality, Thousand Oaks, CA
5. Director of Corporate Microbiologyand EU Quality Operations **AstraZenica-MedImmune Inc**. Frederick, MD
6. Director of Quality Operations, **Watson-Schein Pharmaceuticals**, Inc., Cherry Hill, NJ
7. Director of Quality Control, **Advanced Tissue Sciences, Inc. (ATS),** San Diego, CA
8. Associate Director, Microbiology, **Teva-GensiaSicor Pharmaceuticals**, Inc., Irvine, CA
9. Head Anti-infective **Drug Development**–Tropical Diseases, CIBA-GEIGY, Basle, Switzerland

An acknowledged industry expert in the following areas:

1. Microbiology, aseptic processing, contamination control programs, visible particle control for parenteral products and Devices, visual Inspection processes for parenteral drugs, compliance audits and building quality culture.

2. Data Integrity compliance and sterility assurance for the aseptic manufacturing of drug substance and sterile drug product (small molecules, therapeutic monoclonal antibody vaccines and proteins).

3.Extensive experience with sterile Medical Devices Combination Products.

4. Aseptic manufacturing facility validation conventional ISO5 cleanroom, Isolators and RABS.

Experience and Expertise & Highlights

**Sterility Assurance:** Extensive experience in pharmaceutical, biopharmaceutical (monoclonal antibodies and recombinant therapeutic protein), tissue and sterile drug product manufacturing and aseptic filling processes. Expertise in Terminal Steam sterilization, VHP decontamination, Gamma radiation sterilization and cleaning validation. Environmental monitoring (EM), Hands-on experience in microbial contamination control and Quality by Design (QBD) approaches for microbiological in-process controls (IPC) for upstream and downstream purification for drug substance and drug products. Strong background in sterile filtration process. Microbiological testing, LAL testing and extensive experience in Bioburden control, Invitro and *in situ* cleaning and disinfectant efficacy validation, Mycoplasma and viral testing, Aseptic media simulations process, and container closure integrity testing. Considerable experience in Isolator and RABS, facility environmental-utility monitoring and validations of new aseptic manufacturing fill-finish facility. Strong background in sterile spray dried powder manufacturing and filling and visible particle control and final inspection processes. Data integrity assessments and remediation approaches.

Hands on experience in creating Quality Culture, Culture Change Management, Reducing Human Errors and Excellence in Pharmaceutical Drug Quality.

Regulatory Action Remediation: Interacted with regulatory authorities and resolved Gilead Sciences Inc. San Dimas FDA Warning Letter.

At Schein Pharmaceuticals participate in developing Quality ImprovementPlan (QIP) for correcting Consent Decree and managed the Microbiology-Quality action plans to pass the Consent Decree FDA audit. At Advance Tissues Sciences Inc. (ATS) formulated and managed Quality compliance-remedial plans and remedied the FDA-warning letter.

**Quality-compliance experience**: Developed strategies and successfully led QA/QC and Microbiology departments more than 33 FDA and several MHRA, EMA, IMB, HC and TGA audits.Hands on experience in Quality compliance remediation and continuous Quality improvement plan preparation, resolve investigations, CAPA, personnel training, internal and external audits, and batch release processes. Strong background in QC operations, OOS resolution, Microbiology method validation and method transfer. Hands-on experience of conducting Root Cause Analysis, Risk Assessment, and Risk Prevention-Mitigation.

**Publications:** Several Book chapters and publications in major peer reviewed Journals