

Meet the Expert



Dave has an in-depth knowledge of cell culture science and operations and the design/implementation of Single-Use (SU) technologies; significantly improving operational capabilities, throughput and process control for clients.

Dave offers 30 years of experience as a bioprocess subject matter expert in operations, upstream and downstream, simulation/throughput analysis, process development, engineering, and architecture and overall biotech consultancy. In operations, he has developed small and large molecular weight cell culture products through Ph II, and has provided continuity thru commercial manufacturing.

Most of Dave's operations experience utilized stainless steel systems, but as Single-Use systems evolved he has re-aligned to understand and co-develop their design and use throughout the process.

As an Engineering Fellow and Principal Engineer, his work experience includes process consulting for small- and large-scale R&D and manufacturing projects worldwide ranging from \$5MM - \$100MM.

- Dave designed, implemented and qualified single-use technology for cell culture bioreactor systems, filtration skids, UF/DF and chromatography systems. Acting as an in-house process consultant, he also led the worldwide implementation of single-use technologies- improving operational capabilities, throughput and controls throughout global development and commercial manufacturing operations. The result is the increased probability of shortening 'time to first use' and therefore shortening 'time to market'.
- Dave created tools for analyzing parametrics, organizing the upstream and downstream steps, and presenting the results (material balance, chronology, sampling, costs, etc.) for use by scientists, engineers, and managers to facilitate tech transfer and commercial retrofits.
- Leading an effort for streamlining downstream processing, Dave's (co-inventor) efforts were instrumental in leading to a patent submission and design/build of the first ever system.

Considered an expert in disposable technology and fermentation, Dave has presented at numerous meetings and conferences on topics such as: "Disposables Costs", "Disposable Technologies to Streamline Pre-clinical and Clinical Manufacturing: A Cheaper and Faster Route to Market Launch" and "Biosafety in Technology Today". Most recently, Dave authored a chapter, "Single Use vs. Stainless Steel Systems", in the *Encyclopedia of Industrial Biotechnology* in addition to publishing numerous technical manuscripts.

Dave Wareheim BioProcess Specialist

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Areas of Expertise

- **Single-Use Technologies**
- **Client Successes**
- **Manufacturing Operations Strategies**
- **Operational Improvement**
- **Process Technologies, Development, Engineering, Architecture**
- **Simulation/Throughput Analysis**