Bulk Drug Substance Fluid Transfer

The Challenge
A Bioprocess Engineer at a Monoclonal Antibody Therapy Developer was responsible for employing a sterile process for bulk drug substance (BDS) fluid transfer at their new facility. The objectives of this product development included 1) maximize time efficiency of the critical fluid transfer process, 2) measure in-process pressure, 3) no visible loose particulates USP <788>, 4) sterile (10-6 SAL) and aseptic-processing capability and 5) low endotoxin levels 0.25 EU/ml (USP 85). The customer's implied risk was extremely high during the BDS critical fluid transfer phase of bioprocess. The single-use system requested must provide the very best in fluid path integrity assurance.

The Saint-Gobain Collaborative Design Services' Solution
Customer's new facility and bioprocess innovation requirements were evolving during our Design Services activities and several product design concepts were considered prior to finalization. This bulk drug substance fluid transfer assembly included Sani-Tech® STHT®-65 Silicone Tubing that has a low extractable profile and smooth inner bore surface, Pure-Fit® SC Sterile Connectors for aseptic connectivity in a non-aseptic area, BarbLock® Retainers with 360 degree radial compression and an in-line PendoTECH pressure sensor for in-process monitoring.

Customer Experience
Our dedicated resources and commitment to their bioprocess needs led to meeting their new facility start-up timeline objectives. This development provided our customer greater awareness of our open architecture design capabilities with the implementation of the PendoTech Pressure Sensor.