

E&L – Denaturing of Protein

Product

- Biologic
- Rheumatoid Arthritis
- Commercially available

Issue

- Denaturing of protein in package
 - Thought to be leached transition metal

Resolution

- Not resultant from transition metal
- Identified leached organic compound causing issue
 - Comparison of pure/denatured
 - MS and ICP/LC/GC
- Denaturing source identified/mitigated

