

316: US v. Barr
Pharmaceutical and Biotechnology
(Course length: 2.0 Hours, 19 Graphics, 57 Pages)

Purpose: To learn about the role of QC in the support of manufacturing drug products

Objectives

To state the essence of Judge Wolin's decision regarding:

- UPS Standards
- OOD Procedures
- Retesting
- Re-sampling
- Averaging Results of Analysis
- Remixing
- Product Release
- Blend Testing
- Validation Issues
- Application Approvals



Topics and Activities

1. Introduction and GMP opener activity
2. Wolin's Decision – Standards
3. Wolin's Decision - Out of Specifications
4. Retesting
5. Re-sampling
6. Averaging Analysis Results
7. Remixing
8. Product Release
9. Blend Testing
10. Validation