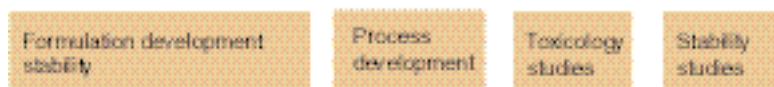


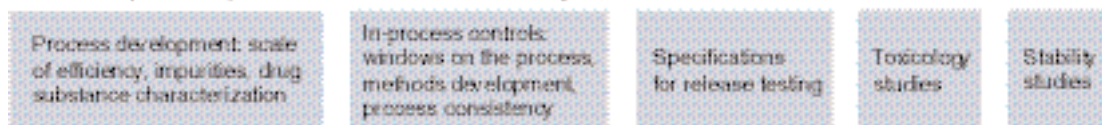
Figure 3. Overview of drug substance development

Lab (Bench) Scale (non-GMP lots)



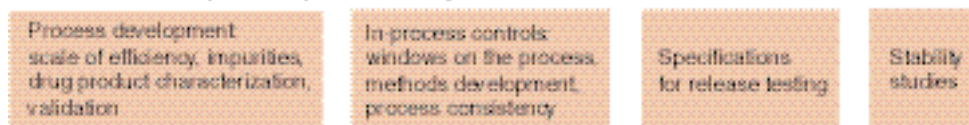
- ↳ Analytical methods development
- ↳ Route of manufacturing changes: scale of efficiency
- ↳ Route of manufacturing changes: impact on changing impurities profile
- ↳ Route of manufacturing changes: physicochemical characterization confirming drug substance
- ↳ Formulation prototype selection and methods validation

Pilot Scale (GMP lots): IND clinical trial material → early launch



- ↳ Route of manufacturing changes: scale of efficiency
- ↳ Route of manufacturing changes: impact on changing impurities profile
- ↳ Route of manufacturing changes: physicochemical characterization confirming drug substance
- ↳ Formulation prototype selection and methods validation

Commercial Scale (GMP lots): NDA Stability Lots → Launch



- ↳ Process validation

Figure 4. Overview of product development

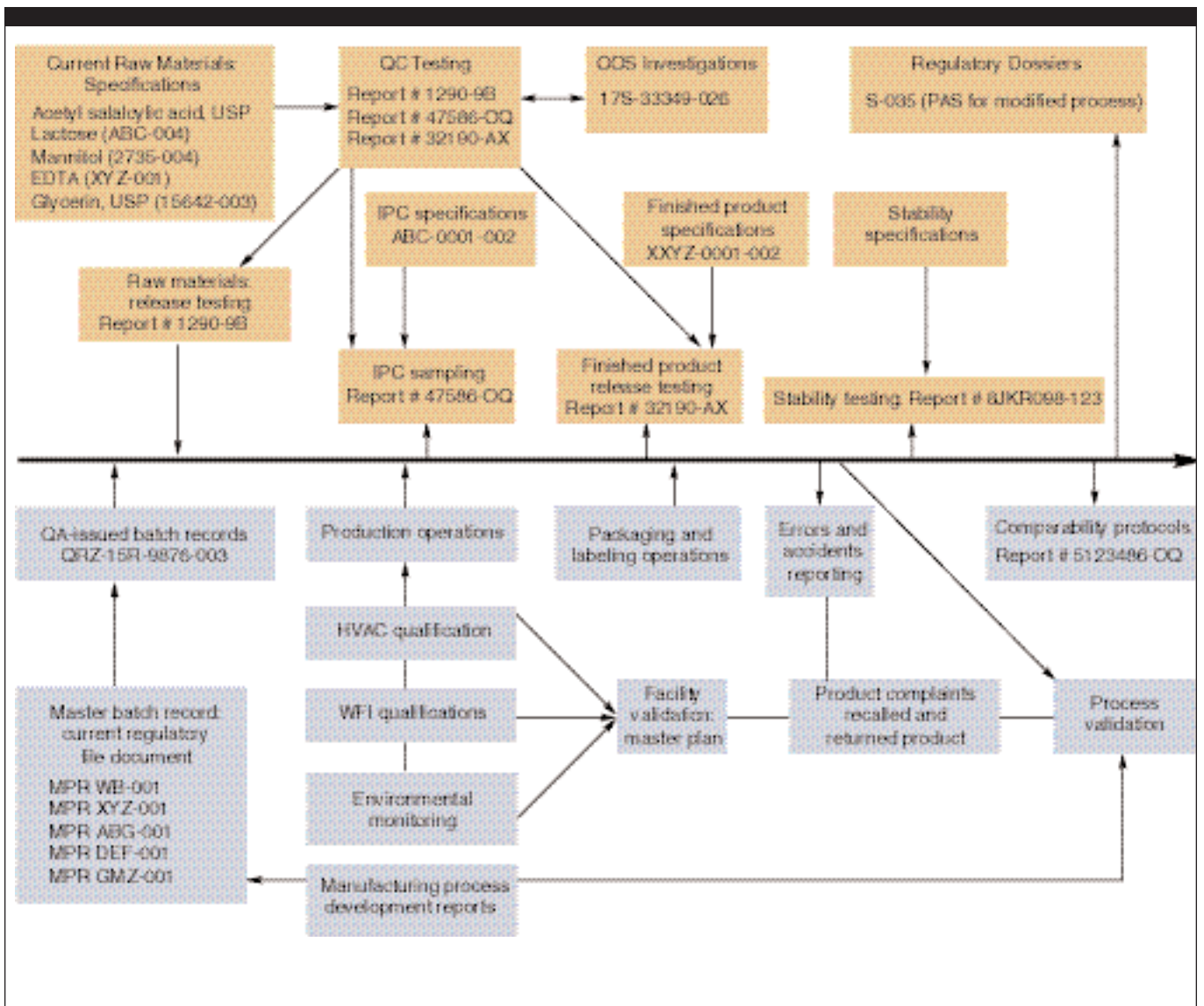


Figure 6. Document mapping