Product Development Process

Proposal
- Product Information
- Process Information
- Regulatory and Clinical Information
- Funding Information
- Contractual Considerations
- Intellectual Property

Assessment
- Opportunity and Strategy
- Clinical Requirements
- Regulatory Pathway
- Compliance Requirements
- Technology Requirements
- Space Requirements
- Contractual Issues
- Cost Estimates
- Biosafety Issues
- Facility DMF

Development
- Process
- Test Methods
- Supplies
- Equipment
- Clinical Strategy
- Documentation
- Budget
- Timeline
- Contract and Billing
- CMC
- Suppliers

Validation
- Timeline
- Validation Plan
- Documentation
- Training
- Test Methods
- Equipment Qualification
- Validation Report
- Validation Approval
- Risk Management
- Budget Review
- Facility Master Plan

Clinical Use
- Product Review
- CAPA
- Clinical Review (SAEs, outcomes)
- Regulatory Compliance
- Quality Monitors
- Financial Review
- Project Review
- Customer Satisfaction