Design & Development – **Key areas detailed**

knoell worldwide registration

Design Documentation

- Definition of **INTENDED USE**
- Compilation of **USER NEEDS**
- Compilation of **DESIGN INPUTS & OUTPUTS**
- Planning of **PRE-CLINICAL VERIFICATION/VALIDATION**

Risk Management

- Planning of **RISK MANAGEMENT**
- Conduction of **RISK ANALYSIS**
- Compilation of **RISK MANAGEMENT REPORTS**
- Post-market **SURVEILLANCE**

Usability

- Creation of **USER INTERFACE CONCEPT**
- Planning of **USER INTERFACE EVALUATION**
- Definition of **USER INTERFACE DESIGN**
- **SUMMATIVE EVALUATION**

Biological Safety

- Conduction of **BIOLOGICAL RISK ASSESSMENT**
- Planning of biological **EVALUATION ACTIVITIES**
- Study **MONITORING**
- Compilation of **BIOLOGICAL EVALUATION REPORT**

Clinical Safety

- Literature search
- Compilation of **CLINICAL EVALUATION REPORT**
- Strategic **PLANNING OF CLINICAL TRIALS** and **POST-MARKET CLINICAL FOLLOW-UP**