IFU Compliance Checklist – Intended Use vs Indications for Use

Intended Use Statement

- Clearly defines the general purpose of the device
- Avoids reference to specific diseases or procedures
- Matches overall design and technical characteristics

Indications for Use Statement

- Specifies disease, condition, or patient group
- Includes intended user and environment of use

Consistency & Compliance

- IFU aligns with labeling, instructions, and marketing materials
- Claims must not exceed the indications cleared or approved by FDA.
- Regulatory impact assessed for any IFU update

Submission & Risk Evaluation

- Reviewed against FDA guidance and 21 CFR 807.92
- Assessed whether change triggers new 510(k) or PMA
- Documented rationale for any IFU adjustment