# Downsizing in Medical Device Companies: Compliance & QMS Continuity Checklist

**Pre-Downsizing Preparation:**

- Identify roles critical to QMS and Regulatory compliance
- Assess documentation at risk of knowledge loss
- Develop knowledge transfer plans
- Document updated org structure with QMS responsibilities

**Immediate Actions Post-Downsizing:**

- Plan for the Management Review meeting after teams have adjusted to the new roles/responsibilities.
- Confirm CAPA, audit, and document control continuity
- Train remaining team members on new responsibilities
- Communicate changes internally and externally (where needed)

**Risk Mitigation:**

- Update risk management file for organizational change
- Ensure QMS documentation reflects current structure
- Schedule internal audit of affected processes within 30 days

**Optional Support:**

- Engage external QA/RA consultants for continuity
- Plan FDA/ISO communication strategy (if needed)