

FDA Medical Device SBOM Compliance Checklist

| | Determine | if your | device | needs | an : | SBOM |
|--|-----------|---------|--------|-------|------|------|
|--|-----------|---------|--------|-------|------|------|

Does your device qualify as a cyber device? That means:

- It includes software.
- It connects to the internet.
- It contains technological characteristics that are vulnerable to cybersecurity threats.

| | \Diamond | If yes, you must submit an SBOM with your FDA premarket application. | | | |
|--|-------------------------------|---|--|--|--|
| | \Diamond | If no, an SBOM isn't required but is still recommended as a best practice. | | | |
| | Inc | lude the 7 NTIA baseline attributes (required for all components): | | | |
| | | Author name | | | |
| | | Timestamp (ISO 8601 format preferred) | | | |
| | | Supplier name | | | |
| | | Component name | | | |
| | | Version string | | | |
| | | Unique identifier | | | |
| | | Dependency relationship (how components relate to each other) | | | |
| ☐ Cover the full software inventory | | | | | |
| | | Include all manufacturer-developed, third-party, and open-source software. | | | |
| | | Include any nested or dependent components your software relies on. | | | |
| | | Use a machine-readable format (e.g., CycloneDX, SPDX, or SWID) unless a spreadsheet is more | | | |
| | | practical for simple SBOMs. | | | |
| ☐ Include additional component-level details | | | | | |
| | | Level of support – is the software still actively maintained? | | | |
| | | End-of-support date – when will updates or patches stop? | | | |
| | Include known vulnerabilities | | | | |
| | | Check each component against databases like the CISA KEV Catalog. | | | |
| | | Include vulnerability information in the SBOM or as a separate addendum. | | | |
| | | Use VeX statements when appropriate to explain why a vulnerability may not apply. | | | |
| For each vulnerability: | | | | | |
| | | Explain how it was found (e.g., scanning tools, manual review). | | | |
| | | Assess the risk to device function and patient safety. | | | |
| _ | | Describe your response, including any compensating controls if a patch isn't possible. | | | |
| | _ | st-market responsibilities | | | |
| | u | Monitor your SBOM over time for new vulnerabilities. | | | |
| | | Update the SBOM as the software changes. | | | |
| | | Notify customers of changes or emerging threats. | | | |
| | u | Include response timelines and metrics in your annual report to the FDA. | | | |
| | | | | | |