

[insert your company name]	Form #:
Supplier Dossier Contents	Effective:
	Supersedes:

Vendor Name: _____*Instructions: check off the following items as they are completed and added into the dossier.***Required**

- ☐ Summary of original evaluation selection and need
- ☐ Basic or short-form vendor questionnaire (esp. if annual)
- ☐ Contract (or similar)
- ☐ Vendor W-9 or other tax form (US only)
- ☐ Purchase order
- ☐ Vendor risk control summary form
- ☐ Vendor re-evaluation form (for renewed suppliers)
- ☐ Dossier contents Records-Location Matrix
- ☐ Qualification summary report

Note: many of these documents may be in other locations (such as contracts in the Legal Department files); simply note their location on this form – or even leave a blank piece of paper in the file that identifies the document's location.

Additional

- ☐ Quality/technical agreement (if separate from contract)
- ☐ Remote audit/due diligence results (for virtual suppliers)
- ☐ Vendor communication matrix
- ☐ Onsite audit report
- ☐ Vendor improvement plan (if any)
- ☐ List of relevant personnel and/or CVs
- ☐ Vendor certifications/accreditations (list or attach copies)

Add rows as necessary – consider adding additional documents referenced in GHTF/IMDRF SG4/N84 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers, Part 5: Audits of Manufacturer Control of Suppliers (2010)

Additional Comments

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