FDA Quality System Regulation For Labelling

To meet the Good Manufacturing Practice (GMP) requirements of the FDA Quality System regulation, device manufacturers must ensure their quality assurance (QA) activities sufficiently cover the labelling requirements too.

- 21 CFR 820.80(b) requires the inspection and testing of incoming materials including labelling
- 21 CFR 820.70(f) requires buildings to be of suitable design and have sufficient space for packaging and labelling operations
- 21 CFR 820.120 deals with specific requirements for the control of labelling

This checklist will help manufacturers to check if they comply with FDA's QS Regulation labelling requirements:

SECTIONS	REQUIREMENTS	STATUS				NOT APPLICABLE
Label Integrity (FD&C 502(f)	Labels remain in place until used	Complies	☐	Does not comply	☐	
	Labels remain legible until used	Complies	☐	Does not comply	☐	
	Print remains legible during storage	Complies	☐	Does not comply	☐	
Receipt and Inspection (21 CFR 820.80 and 21 CFR 820.120)	All packaging and labelling materials are examined	Complies	☐	Does not comply	☐	
	Acceptance activities are performed to assure conformance	Complies	☐	Does not comply	☐	
	Sample labels are proofread by a designated individual	Complies	☐	Does not comply	☐	
	Acceptance activities are recorded in device history record	Complies	☐	Does not comply	☐	
Area Separation and Inspection	Labelling and packaging operations are separated	Complies	☐	Does not comply	☐	
	There are no mix-ups between similar products or labels	Complies	☐	Does not comply	☐	
	For different devices, labelling and packaging are preferably performed at different times	Complies	☐	Does not comply	☐	
	Production area and equipment is clear of previous operation labels and other materials	Complies	☐	Does not comply	☐	
	Unused labels, if any, are destroyed and documented	Complies	☐	Does not comply	☐	
Storage (21 CFR 820.120)	Printed packaging and labelling materials are stored in an area to prevent mix-ups	Complies	☐	Does not comply	☐	
	Labelling materials are identified and segregated to prevent mixing with similar labelling	Complies	☐	Does not comply	☐	
	Access to labelling is limited to authorized personnel only	Complies	☐	Does not comply	☐	
Label Check and Record	Contents of the labelling comply with the specifications	Complies	☐	Does not comply	☐	
	Preferably labels have control numbers	Complies	☐	Does not comply	☐	
	Label should identify fit for use date	Complies	☐	Does not comply	☐	
Changes (21 CFR 820.30(i)	All changes to labelling are made under a formal change control system	Complies	☐	Does not comply	☐	
	Changes to labelling are formally reviewed and authorised	Complies	☐	Does not comply	☐	

Relabeling & Over-labelling	Over-labelling by placing a new label on the previous label is not being done	Complies	☐	Does not comply	☐	
	In case of relabelling, it meets the GMP requirements for legibility, reprocessing, and change control	Complies	☐	Does not comply	☐	
Control Number (21 CFR 820.65)	Surgical implants have a control number present on each unit	Complies	☐	Does not comply	☐	
	A control number is present on each unit, lot, or batch of finished devices for traceability	Complies	☐	Does not comply	☐	
	A control number appears on the unit label that goes to the ultimate user to ensure traceability	Complies	☐	Does not comply	☐	
	Lot no. or Batch no. facilitates failure investigation or product recall	Complies	☐	Does not comply	☐	
Sterile Device Labelling	"Sterile" is mentioned on the primary label	Complies	☐	Does not comply	☐	
	Caution statement is identified	Complies	☐	Does not comply	☐	
	"Method of Sterilization" is indicated by a proper symbol	Complies	☐	Does not comply	☐	
	"To be sterilized before use" is mentioned, if applicable	Complies	☐	Does not comply	☐	
	"Single use device" is indicated by a proper symbol	Complies	☐	Does not comply	☐	
	In case of device kits, sterile and non-sterile contents are clearly identified and separable	Complies	☐	Does not comply	☐	
	Instructions to open the package are provided to avoid contamination	Complies	☐	Does not comply	☐	
Device Labelling – IVD (21 CFR 809.10	Package insert for IVD contains the revision date	Complies	☐	Does not comply	☐	
	Expiration date in case of battery or diagnostic reagent is incorporated	Complies	☐	Does not comply	☐	
	Labelling for in vitro diagnostic has the expiry date	Complies	☐	Does not comply	☐	
	Lot no. or Batch no. to facilitate failure investigation or product recall	Complies	☐	Does not comply	☐	

References:

A. FOOD AND DRUG ADMINISTRATION, CHAPTER H - MEDICAL DEVICES ; Subpart H - Acceptance Activities – 21 CFR 820.80 Receiving, in-process, and finished device acceptance.

B. FOOD AND DRUG ADMINISTRATION, CHAPTER H - MEDICAL DEVICES ; Subpart K - Labelling and Packaging Control – 21 CFR 820.120 Device labelling

C. FOOD AND DRUG ADMINISTRATION, CHAPTER H - MEDICAL DEVICES ; Subpart C - Design Control – 21 CFR 820.30 Design controls

D. FOOD AND DRUG ADMINISTRATION, CHAPTER H - MEDICAL DEVICES ; Subpart F - Identification and Traceability – 21 CFR 820.65 Traceability

E. FOOD AND DRUG ADMINISTRATION, CHAPTER H - MEDICAL DEVICES ; Part 809 - IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE Subpart B – Labelling – 21 CFR 809.10 Labelling for in vitro diagnostic products

For further queries or support, please contact: marketing@compliancequest.com

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