PathWise

Device History Records – What Should They Include?

FDA requires the use of a Device History Record (DHR) for Medical Device manufacturing. The ISO 13485:2016 standard; however, does not specify a "DHR" section. What should be included in a DHR? What DHR content is compliant with 21 CFR 820 and ISO 13485:2016?

This White Paper focuses on Medical Device compliance per 21 CFR 820.184 and ISO 13485:2016 § 4.2.1, 7.5.1, 7.5.8, 7.5.9.1 and 8.2.6 for DHR documentation. The intent is to demonstrate what to include in DHRs that will be compliant with 21 CFR 820 as well as ISO 13485:2016.

What is a Device History Record (DHR)?

21 CFR 820.3 (i) provides the following definition:
Device history record (DHR) means a compilation of records containing the production history of a finished device.
21 CFR 820.184 Device history record explains that each manufacturer shall maintain DHRs. Each manufacturer shall establish and maintain procedures to ensure that DHR's for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the DMR (Device Master Record) and the requirements of 21 CFR 820.184. The DHR shall include, or refer to the location of:

(a) The dates of manufacture;
(b) The quantity manufactured;
(c) The quantity released for distribution;
(d) The acceptance records which demonstrate the device is manufactured in ac cordance with the DMR;
(e) The primary identification label and labeling used for each production unit; and
(f)Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used.

What is the ISO 13485:2016 requirement for a DHR?

DHR is not specifically detailed in ISO 13485:2016. This standard; however, details the same / similar content. The most notable section is:

- ISO 13485:2016 § 7.5.1, which includes control of production and service provision. It explains that production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. It details controls such as:

a. Documentation of procedures and methods for the control of production (Control of Documents);
b. Qualification of infrastructure;

c. Implementation of monitoring and measurement of process parameters and product characteristics;
d. Availability and use of monitoring and measuring equipment;
e. Implementation of defined operations for labelling and packaging;
f. Implementation of product release, delivery and post-delivery activities

This section further explains that the organization shall establish and maintain a record for each medical device or batch of medical devices that provides traceability and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.

Also worth noting are:

- ISO 13485:2016 § 4.2.1 includes general documentation requirements that are also applicable to DHR.
- ISO 13485:2016 § 7.5.8 discusses identification. The organization shall document procedures for product identification and identify product by suitable means throughout product realization. This includes a system to assign unique device identification to the medical device, where required by applicable regulatory requirements.
- ISO 13485:2016 § 7.5.9.1 discusses general requirements for traceability that are also applicable to DHR.
- ISO 13485:2016 § 8.2.6 discusses monitoring and measurement of product to verify that product requirements have been met. This shall be carried out at applicable stages of product realization. Evidence of conformity to the acceptance criteria shall be maintained, with the identity of the person authorizing release of product recorded. Product release and service delivery shall not proceed until the planned and documented arrangements have been satisfactorily completed. For implantable medical devices, the organization shall record the identity of personnel performing any inspection or testing.

How Are These Similar?

The compilation of records meeting the requirements of the above ISO sections, could also be referred to as a DHR. Although there are slight differences in how they are outlined from the FDA regulation to the ISO standard, the overall intent is the same. Each system is requiring the Medical Device Manufacturer to maintain a production record. This production record is applicable to each batch, lot or unit (as appropriate).

DHR Contents

For Medical Device companies that are both FDA Registered and ISO 13485:2016 certified, it's possible to create a single DHR system that addresses the FDA and ISO requirements. Within this single system, it is important to establish and maintain relevant DHR procedures, ensuring that DHRs are maintained to demonstrate that the device is manufactured in accordance with the Device Master Record (DMR) / Medical Device File (MDF), using appropriate production controls.

The following DHR content is applicable to include or reference (as applicable):

1. DHR creation (per batch / lot / unit) based upon Device Master Record (DMR) / Medical Device File (MDF), following appropriately established and maintained procedures;
2. The dates of manufacture;
3. The quantity manufactured;
4. Traceability details (part / lot information for product as well as components and relevant consumables);
5. Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;
6. The primary identification label and labeling used for each production unit;
7. The acceptance / inspection (monitoring and measurement) records which demonstrate the device is manufactured in accordance with the DMR / MDF (specification), at applicable stages of production. Records to identify test equipment used to perform measurement activities, as appropriate. For implantable medical devices, records shall also include the identity of personnel performing inspections / testing;
8. The quantity released / approved for distribution;
9. DHR record requires verification and approval prior to product release and service delivery. The identity of the person authorizing release of product shall be recorded;
10. Retain DHR according to relevant record retention requirements.

Of course, DHRs can be customized based upon individual company / product requirements, as long as the core DHR requirements continue to be met. This can take place by the use of Enterprise Resource Planning (ERP) / Material Requirements Planning (MRP) systems, the use of routers, picklists, reconciliation sheets, etc. In cases where there are deviations, non-conformances, etc. identified during the production process, these records are also relevant to include or reference in the DHR.

Summary

The FDA requires the use of DHRs for Medical Device manufacturing. ISO 13485:2016 does not specify a “DHR” requirement; however, it does identify similar requirements for the establishment and maintenance of manufacturing records. As applicable, it is possible to create a system with contents that address the requirements of FDA as well as ISO, in a single DHR format.

ABOUT THE AUTHOR:

Nola Benstog is a diversified professional with a thorough knowledge of Quality Management Systems. She has over 16 years of experience in the areas of Quality Assurance, Quality Control, Regulatory Affairs, Validation, and Sterilization in both industry and consulting roles. She has worked in the medical device, pharmaceutical, combination product, and nutritional supplement industries with experience ranging from start-ups to Fortune 500 Companies. She has held various positions up to the Executive Management level throughout her career. Nola received a Bachelor of Science in Microbiology from Weber State University and a Master of Business Administration from the Utah State University. She has been an American Society for Quality (ASQ) Certified Quality Auditor (CQA) since 2007.