Quality Audits

The Context
Device manufacturers, as part of the QMS must, implement an internal quality audit program based on the requirements in §820.22. The program should be comprehensive so it audits all of the QMS elements using trained auditors. The program assigns auditors "who do not have direct responsibility for the matters being audited".

The Warning Letter
FDA sent this March 4, 2016 Warning Letter to DMP Ltd. a manufacturer of dental impression materials and composite resins located in Markopoulo, Greece. The Warning Letter was the result of an FDA inspection.

The Issue Cited
The Warning Letter cited a failure to follow the firm's own procedure for assigning auditors. The citation says, "[Y]our firm's procedure "Internal Audit" … requires the Quality Manager to designate auditors who are independent of the section or process that is being audited. However, the individual who conducted the quality audits for 2014 and 2015 had direct responsibility for the document control and complaint handling activities being audited."

The DMP responded and FDA said, "We reviewed your firm's response and conclude it is not adequate. The response indicated your firm has revised [your procedure] and the organizational chart to clarify responsibilities. Additionally, the response indicated the management representative was trained in the revised [procedure]. Finally, the next internal audit has been scheduled using the new SOP. However, the response did not indicate how your firm plans to identify and train all appropriate staff."

The Requirement
The Quality System Regulation requires, in §820.22, "Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited."

Both ISO 13485:2003 and ISO 13485:2016 have a similar requirement.

> Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. [ISO 13485:2003, 8.2.2]
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> The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. [ISO 13485:2016, 8.2.4]

Recommendations
Develop a comprehensive internal quality audit program to ensure the QMS complies with quality system requirements and that it is effective.

In terms of auditors, establish competence requirements and ensure that auditors are competent to conduct the audits assigned to them. Create records that provide objective evidence of competence.

In terms of auditor assignments, understand the areas for which the auditor has “direct responsibility”. There is a question, unanswered in the regulation, about direct versus indirect responsibility.

One way to answer it uses the organization chart. Determine where the area for the audit falls in the organization chart. In addition, determine where the prospective auditors dally work falls in the organization chart. If the potential auditor’s responsibility were in any “box” from the area to audit up to top management, best practice would avoid that assignment.