CPG Sec. 390.425 Records and Reports; Applicability - 21 CFR 1002.1

BACKGROUND:

Because of cooperative or contractual arrangements between certain manufacturers and/or distributors of an electronic product, it is not clear who is required to submit the required reports for the product pursuant to *21 CFR 1002.1.* For example ABC Corporation designed a laser product, tested prototypes, contracted the manufacture of the product to XYZ Corporation, and supplied some but not all of the components for manufacture to XYZ. XYZ then shipped all finished units to ABC which in turn only distributes through another company. Which company is responsible for maintaining records and filing reports?

POLICY:

ABC, as the firm which owns the design and lets the manufacturing contract is responsible for maintaining the records and submitting reports to the *Center for Devices and Radiological Health.* It could, however, through arrangements with XYZ, designate XYZ to develop certain records and reports related to XYZ's share of the manufacture and quality control of the product. If certain of the information required in the records and reports is *unique* within the experience of XYZ Corporation, XYZ will have to provide this information to ABC Corporation in order for a report filed by ABC to be complete. ABC still maintains responsibility for submitting the reports to FDA.

Material between asterisks is new or revised

Issued: 10/1/80
Revised: 3/95

More in Compliance Policy Guides (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm)

Foreword: Compliance Policy Guides (CPGs) (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116271.htm)

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