Recent Efforts of Quality management system for medical devices in Japan

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Inspection Trend

- Risk assessment for products types, manufacturing processes, adverse events etc.
- QMS regulation harmonized to ISO 13485: 2016 and added requirement for reprocessed single-use medical devices
- Utilization of MDSAP reports
- MOC with Taiwan for simplification of inspection

矢部3

★ Enhance interaction to review/safety department
★ Increase high skilled inspectors

→ Enhance quality of our inspection

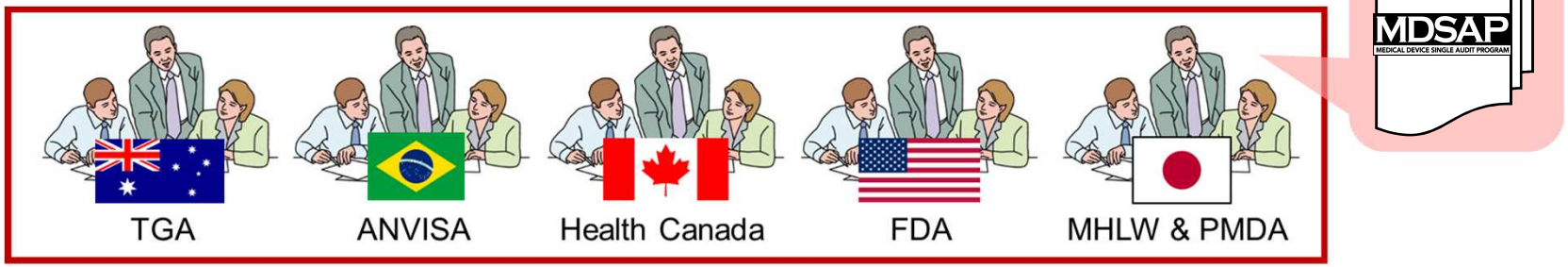
スライド 2

矢部3　2016Verに対応するための通知の話、省令改正の準備の話を、いずれも口頭で必要です

矢部 仁美, 2018/11/20

Participation in MDSAP

MDSAP: Medical Device Single Audit Program



◆Utilization of MDSAP audit reports respecting the sovereignty of each authority by MDSAP regulators

◆Acceptance of MDSAP reports in initial or recertification inspection ※ As a trial, surveillance report, and initial or recertification audit report published under CMDCAS can be accepted.

矢部8

◆Performing of off-site inspection instead of on-site inspection or reducing documents to submit for off-site inspection.

スライド 3

矢部8　定義について口頭で説明必要
矢部 仁美, 2018/11/20

Training in Asia

QMS Area

●Training and/or Case study of QMS inspection

・PMDA-ATC Medical Devices Seminar in PMDA (July 2018)

・2nd Dispatched Expert Program in Thai-FDA (September 2018)

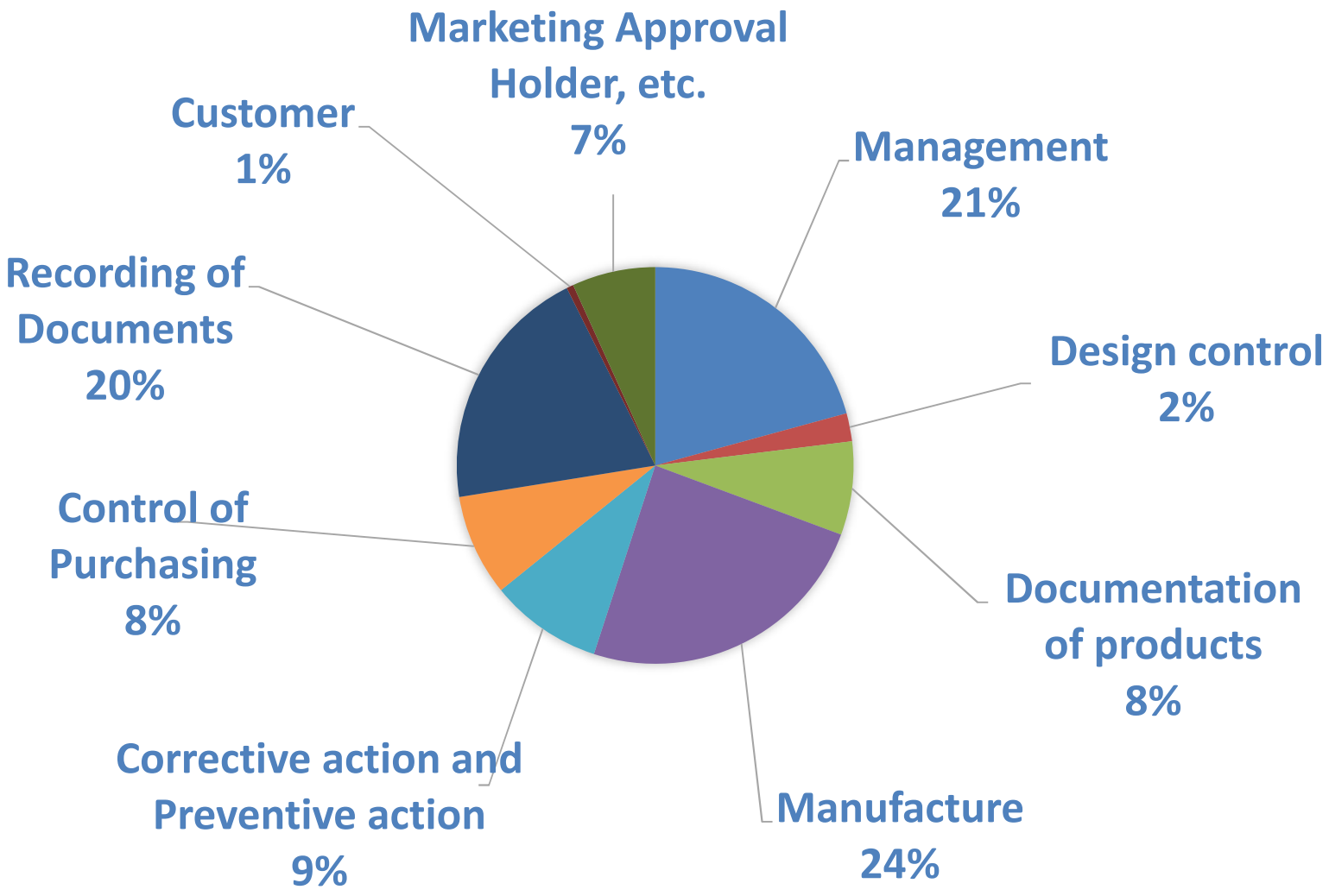
・PMDA-ATC Medical Devices Seminar in PMDA (November 2018)

矢部1

スライド 4

矢部1　横山さんに集合写真依頼中
矢部 仁美, 2018/11/20

Nonconformity of on-site inspection



Thank you for your attention.

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