Quality Certification on Medical Devices and Pharmaceuticals

Proposal from Industry (Medical Devices)

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Industry Perspectives on MDSAP utilization

- Japanese QMS audit utilize MDSAP audit report . Basically, in this case on-site audit will be exempted, and the required documents will be also reduced than regular audit.

- Number of application for utilizing MDSAP audit report for Japanese QMS audit is yet a little at this moment, but the Japanese company who exports products globally has much interest in MDSAP.

  ⇒ JFMDA held MDSAP seminar for Japanese industry last year and it was well-attended almost 500 people (full capacity of the venue).

  ⇒ JFMDA QMS Committee has regular meeting with our authority (MHLW, PMDA) for MDSAP operation.

Questions from JFMDA

- We would like to appreciate that many problems are solved or improved by the great effort of ANVISA for GMP/QMS audit issue.

- But we would like to ask following items about the efficiency of utilizing MDSAP certificate and audit report (ANVISA's Policy, Current Situation, Future Plan).

  ⇒ How much time has been shortened approximately by using MDSAP audit report, from the submission to issuance of ANVISA certificate?

  ⇒ How do you think about the MDSAP certificate taking place of the ANVISA GMP certificate, like the Canadian case? Is there any possibility for that?

  ⇒ Future plan for facilitating the MDSAP utilization.