Organizational Developments and FDA Office of Partnerships’ Activities for Pharma and Medical Devices – Current and Future

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AFDO Annual Conference
Houston, TX
June 20, 2017
Topics Covered

• Geographically and Program Aligned Org Charts
• OP Organization, Pre and Post Program Alignment
• 2017 MQSA Contract Program
• 2017 Medical Device Contract Program
• Potential OP Future Activities for Pharma and Medical Devices
• Questions
Geographically Aligned Organizational Model
Program Aligned Organizational Model

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Organizational Chart (Pre-Program Alignment)

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MQSA Contract Program

• Congress mandated there be annual reporting of adverse actions taken against mammography facilities; Mammography Quality Standards Act (MQSA, Oct. 1992)

• Reports must include information that is useful in evaluating the performance of mammography facilities nationwide

• The Act requires the establishment of a federal certification and inspection program for mammography facilities

• The contract program is intended to assist state and local authorities in the inspection of certified non-federal mammography facilities
MQSA Contract Program (Continued)

**MQSA Contract States FY16**

- 41 States
- + Puerto Rico
- + New York City

**FY16**

**Program Metrics**

- Current program funding: $9,720,997.20
- Current number of awards: 43
- Average cost per contract: $218,089.69
- Average number of inspections per contract: 154
- Total number of contracted Inspections: 6,935
Medical Device Contract Program

• This funding program provides state assistance in the inspection of Class I and Class II medical device manufacturers

• Inspections determine if faculties management has ensured that an adequate and effective quality system has been established (defined, documented, and implemented at the firm)

• By entering into these contracts, district workload can be converted from an inspectional role to a minority role
Medical Device Contract Program (Continued)

**FY16**

**PROGRAM METRICS**

- Current program funding: $267,248.86
- Current number of awards: 2
- Average number of inspections per contract: 28
- Total number of contracted inspections: 56
Potential OP Future Activities for Medical Devices

• Development and execution of a global medical device program workplan based on enhanced risk criteria evaluation
• Development, execution, and strategic planning for a national mammography program
• Establishment of the inspectorate capability to support a business case for annual work planning
• Development of curriculum within the program that supports sub specialty development and expertise
• Establishing training vehicles and options that complement OTED programs while advancing the sub specialization development for investigators and compliance officers
Potential OP Future Activities for Pharma?
Questions?
Feedback

• OP welcomes your feedback on this presentation and any services provided by OP

• Any feedback provided to this address will be reviewed by the Director of Office of Partnerships

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