# Update on China-Denmark Food and Drug Regulatory Cooperation Centre

## Stakeholder meeting, 14 June 2019

Jakob Cold, Deputy Director General, Danish Medicines Agency


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# State of Play

- Strategic Sector Cooperation on Health in China (SSC Health China) approved by DK MFA on 11 March 2019
- First activities of Strategic Sector Cooperation on Health in China (SSC Health China) – Medicines carried out
  - Exchange Forum on Quality Documentation in Clinical Trials, March 2019
  - Exchange Forum on Medical Device Frameworks in CN and DK, April 2019
- Preparation of more activities of the SSC Health China
- MAH International Seminar, Beijing, 29 March 2019

# Exchange Forum on Quality Documentation in Clinical Trials, Beijing, March 2019

- 2 days exchange forum on Quality Documentation in Clinical Trials at CDE
  - Both chemical and biological medicines
  - IMPD requirements and assessment, active substance and finished product, changes to documentation, definition of biological medicines, FIH trials
  - Main focus on biological medicines
- 2 DKMA experts
- Up to 60 CDE participants, most for chemical medicines
  - Small group of senior assessors, many junior assessors

# Exchange Forum Quality Documentation in Clinical Trials, March 2019




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# Exchange Forum Quality Documentation in Clinical Trials, March 2019




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# Exchange Forum on Medical Device Frameworks, April 2019

- 2 days exchange forum on Medical Device Frameworks in CN and DK at CMDE
  - Overview of frameworks, classification/risk classes, clinical investigation approval, market surveillance, laboratory control, challenges from new technology
  - Get to know each other's systems
- 3 DKMA experts and DKMA project manager
- 25-30 CMDE staff
  - Plus NMPA, NIFDC and National Centre for Adverse Drug Reaction Monitoring
- CN focus: reforms, innovative MDs, optimise procedures and processes (ISO standard)
  - Increase in staff, MDs and MD manufacturers
- Explorative meeting with CMDE at technical level
  - Adjustments to work plan

# Exchange Forum on Medical Device Frameworks, April 2019




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# Exchange Forum on Medical Device Frameworks, April 2019




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# SSC activities in preparation

- NIFDC visit 1-4 July on radiopharmaceuticals
  - 3 full days, 2 NIFDC experts
  - Preparation for PTS on radiopharmaceuticals this autumn
- Exchange Forum on GCP inspection of sponsor, September 2019
  - 2 DKMA inspectors
  - CFDI
- Exchange Forum on assessment of biological and biosimilar medicines, September 2019
  - 2-3 DKMA experts, both clinical and quality assessment
  - CDE
- Internal discussion on staff exchange with CDE

# Ambitious workplan

## 25 activities in 2019-2021 within the areas of:

- Information exchange and *best practice sharing* on the development and implementation of drug regulatory frameworks and standards.
- Licensing and authorization procedures for drugs and medical devices.
- Market surveillance, inspections, safety reporting and product recalling
- Guidelines, laboratory testing, control procedures, accreditations
- Exchange on quality management and personnel training

## Modes of cooperation:

- Exchange of information on policies, laws and regulations
- Joint seminars, workshops, virtual meetings and technical training
- Exchange visits

# MAH International Seminar, 29 March 2019

- Hosted by NMPA with leaders from NMPA, Law Committee of National People's Congress and Ministry of Justice
- Purpose: promote further understanding of MAH concept and help in review of Drug Administration Law
  - Opportunity to consult experts and for stakeholders to provide input
- DKMA expert participated together with authority experts from US FDA, PMDA and EU Delegation
- Stakeholders presented on the practice of MAH in EU, US and Japan

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