Jaap Boes
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Toxicology and Safety Assessment of cosmetics, food additives and medical devices

ID1002

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medicologic®
Medical Device Development

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Competences

- Toxicology (AIHA certificate)
- Product Information File (PIF, cosmetics)
- Risk analysis (Codex Alimentarius, OIE standards)
- Safety assessment (ISO 10993 standards)
- Clinical evaluation (WMDO certificate)
- Multi-disciplinary project management
- Strategic planning and execution
- National and international grant applications
- External examiner at Copenhagen University
- Experience with Balanced Score Card

Key results

- Clinical Evaluation Reports on medical devices (face masks, resuscitators) as part of MDR transition
- Biological Evaluation Report on a suction/irrigation device for laparoscopic surgery
- Biological Evaluation Reports on CBD based products for treatment of psoriasis and arthritis
- Biological Evaluation Reports on hearing aids
- Clinical and technical reviews to Notified Bodies as part of transition from MDD to MDR
- Post-Market Clinical Follow-up plans and reports

Regulations/Standards

- Safety assessment of cosmetic products (ingredients) and Product Information File (PIF)
- Clinical evaluation according to MDR regulations and MEDDEV 2.7.1 rev. 4: author and evaluator of Clinical Evaluation Plans and Reports (WMDO certified)
- Trained in Biological Evaluation, Clinical procedures, Design control, Risk management
- ISO 10993 for biosafety of medical devices including toxicological safety assessments (AIHA certified) and Biological Evaluation Reports
- Risk assessments for food safety and animal health according to OIE and Codex Alimentarius standards

Research methodology

- Design of clinical studies including regulatory aspects and statistical analysis
- Literature search (Medline, PubMed, Google Scholar) and data appraisal
- Scientific reporting / medical writing: 30+ peer-reviewed scientific articles, presentations at international scientific conferences including a PhD degree and two systematic reviews
- Author of successful grant applications (DK national, EU)

References

Medicologic A/S 2020 – present:

GN Hearing – 4 days/week for 7 months
- Biological Evaluation and Risk Assessment of Medical Devices

AMBU – full time for 9 months
- Biosafety and Risk Assessment of Medical Devices
- Clinical evaluation of Medical Devices

JBO Consult:
- Safety assessments of medical devices
- Risk assessment for food safety
- Clinical trials, Scientific reviews, grant applications
- Project development, project management

SEGES Livestock Innovation:
- Risk assessment for food safety and diseases
- Surveillance programs for animal diseases and antibiotic usage and resistance

Danish Agriculture & Food Council:
- Risk analysis for food safety
- Clinical trials of veterinary medicine
- Innovation projects on food safety and animal diseases
- Coordination of public-private R&D projects between academia and agriculture
- Publication of results in peer-reviewed scientific journals