# Preparing for EU MDR in a Pandemic?

Presented by GForce Life Sciences, Malkan Solutions, and SunTrix Medical Consulting

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SunTrix Medical Consulting

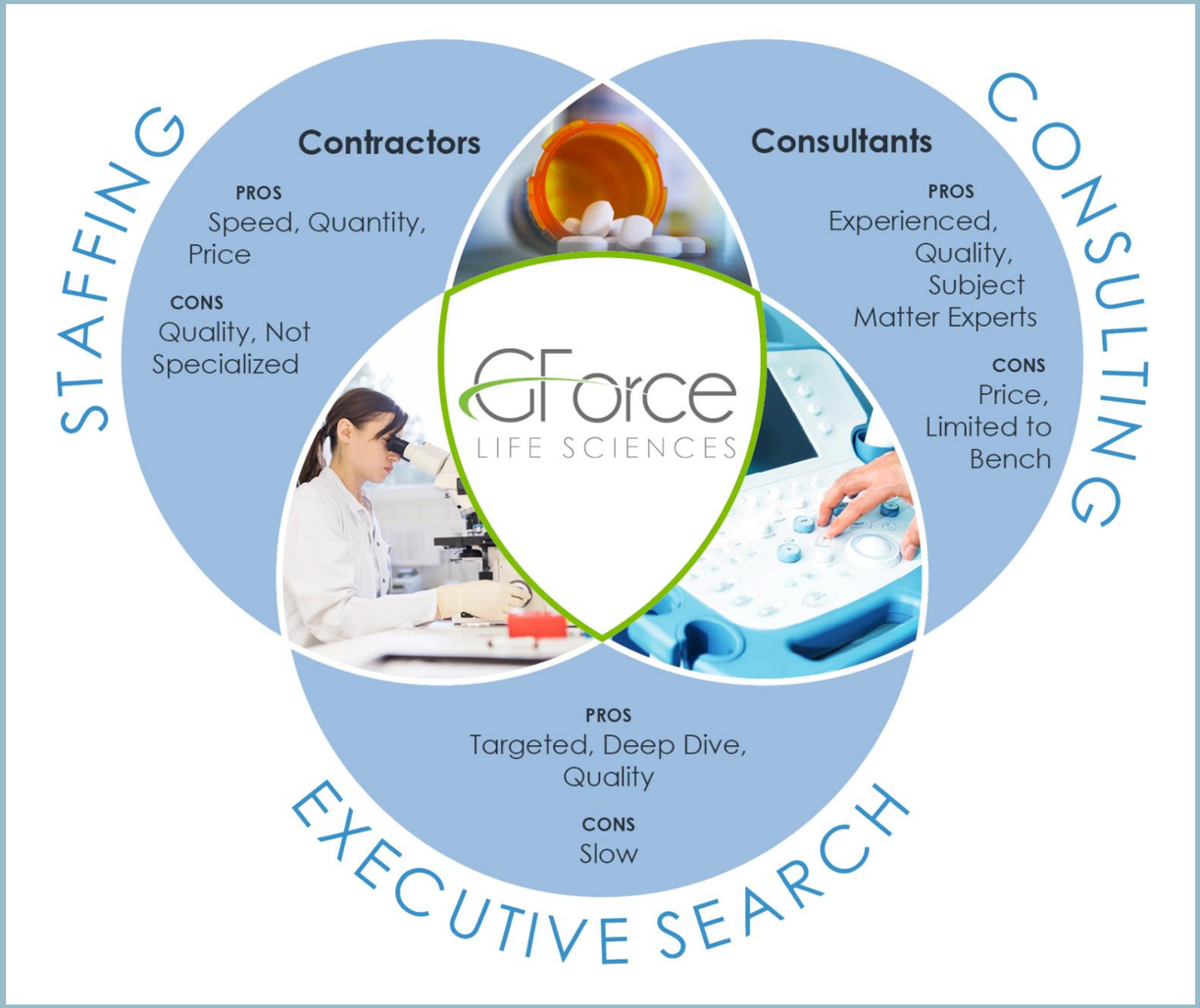
# Questions

- Thank you for your questions submitted during registration!
- You are still able to ask questions during the webinar and they may be answered in the follow-up Q&A
- If you have a question after the webinar, you can still email jwebber@gforcelifesciences.com
- Reminder: you will be notified via email when the slides and webinar recording are available (within 24 hours)

# Host – John Webber

- President, GForce Life Sciences
- 20 + years in services (consulting, staffing)
- Match highly targeted consultants to executives' needs in life sciences (medical device, pharma, biotech, diagnostics)
- #8 Fastest Growing Company in America in 2018 (Inc. 500)
- Best Company to Work For (SIA, Illinois)
- 97.3/100 Net Promoter Score – Consultant rated
  - Industry Average: 18.4!

# Speed, Experience, and Targeted Search



# Services

### Project & Program Management

- Program & Project Planning
- Resource Allocation & Management
- Budget Establishment, Analysis & Tracking
- Project Scope Definition
- Coach, Mentor & Train others PMs
- Functional Leaders & Team Members
- Success Measures & Metrics (Dashboards)
- Assessments
- PMO & PPM
- Help develop your DFM & AS
- Environmental PFMEAS

### Quality

- Quality Management Systems
- Deviation & CAPA Management
- Process Design, Harmonization & Validation
- QA/QC
- Remediation Services
- Unique Device Identification (UDI)
- Design History File (DHF)
- Device Master File (DMF) & Device Master Record (DMR)
- Validation
- Mock FDA Audits
- Sterilization
- Computer Systems Validation

### Supply Chain & Manufacturing

- Operations & Manufacturing Strategy & Process Excellence
- Technical Transfer
- Innovation & Product Development
- Sourcing & Procurement
- Integrated Planning & Analytics, Logistics, Quality & Supplier Compliance
- Knowledge Capital
- Implementation Accelerators
- Analytics & Mobility
- Control Towers
- Contract Manufacturing
- Six Sigma
- TPM
- Supplier Audits & Remediation

### Regulatory

- FDA (483 Observations, Warning Letters, COnsent Decrees) Remediation
- Submissions (Premarket Approval PMA, 510 (k), CE Mark & Compliance
- Technical File & Design Dossier Preparation
- Labeling, Packaging, Advertising & Promotional Materials
- UDI
- Global Regulatory Needs

# Services

### Research & Development

- Clinical Trial
- Product Development Process
- Total Quality by Design
- Process Development
- Design Controls
- Risk Management

### Audits

- Quality Management System (QMS)
- GMP
- Baseline or Gap Assessment
- Inspection Readiness
- MDSAP Compliance Readiness Assessments
- Supplier/Distributor
- Contract Manufacturer
- ISO 9001, 13485, 14971
- 21 CFR Part 820
- 21 CFR Part 11
- Auditor Training

### Medical Affairs

- Health Economics & Outcomes Research (HEOR)
- Compliance
- Medical Safety Development
- Information Services
- Communications
- New MDR Requirements
- Education

### MDR/IVDR

- Program/Project Management
- Quality System Gap Assessment
- Product Gap Assessment
- Creation/generation of complaint procedures, work instructions and templates to support a compliant MDR and/or IVDR system
- Workshop facilitation, training and communication
- Remediation: Post-Market Surveillance, Clinical Evaluation Reports, Product Technical Files and Design Dossiers

# Kashyap Malkan

- Principal, Malkan Solutions
- ASQ Certified Auditor
- PMI Project Management Professional
- BS, MS Engineering & Quality
- 19+ years with Fortune 500 medical device manufacturers (and others)
- Multiple roles in Engineering, Sourcing and Quality
- 14+ years of auditing experience
- Six Sigma Blackbelt
- Lean Leader

# Armin Beck

- CEO of SunTrix Consulting LLC & Co-founder; COO/Executive VP CA/QA/RA of Vasoflow
- SunTrix is a consulting firm specializing in Quality/Regulatory/Clinical Affairs and overall Quality System Compliance for the Medical Device industry.
- SunTrix is recommended by Medcert, a German Notified Body, as a consulting company for all European Regulatory, Clinical and Quality Affairs matters.

# New Regulations: Preparation

- Date of application of the Medical Devices Regulation postponed until May 2021
- On 26 May 2021, the Medical Device Regulation will become fully applicable, following the transition period. Please keep the revised deadline firmly in mind.
- The corresponding date of application of the In Vitro Diagnostic Medical Devices Regulation (IVDR, Regulation (EU) 2017/746) remains in May 2022.

# Who oversees the MDR/IVDR?

## EU Commission

- Develop Legislation and Guidance
- Support member states
- Modify legislation through delegating and implementing acts
- Setup and Manage
- EUDAMED
- Medical Device Coordination Group
- Develop and publish common specifications

## Member State (Competent Authority)

- MDR Enforcement no transposition
- National Law enforcement
- Designate Notified Bodies
- Audit manufacturers

## Notified Body

- Conformity Assessment of Manufacturers, suppliers and subcontractors
- Audit manufacturers

## Manufacturer and other Economic Operators

- CE Mark Devices
- Responsible for Medical devices– Declaration of conformity

# After the Transitional Period: New Rules!

- The new regulations contain a series of extremely important improvements to modernize the current system.

Among them are:

- Stricter previous control for high-risk devices via a new pre-market scrutiny mechanism with the involvement of a pool of experts at EU level
- Reinforcement of the criteria for designation and processes for oversight of notified bodies
- Inclusion of certain aesthetic devices that present the same characteristics and risk profile as analogous medical devices under the scope of the regulations
- New risk classification system for in vitro diagnostic medical devices in line with international guidance

# After the Transitional Period: New Rules!

- Improved transparency through a comprehensive EU database on medical devices and a device traceability system based on a unique device identification
- Introduction of an ‘implant card’ for patients containing information about implanted medical devices
- Reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorizing multi-center clinical investigations
- Strengthening of post-market surveillance requirements for manufacturers
- Improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance

# Brexit - What's Next for Medical Device

- It was supposed to happen on March 29, 2019, then October 31, 2019. It finally did happen on January 31, 2020. Brexit is finished.
- The UK is no longer a member of the European Union. UK includes England, Wales, Scotland and Northern Ireland but not Ireland which is part of the EU.
- The UK MHRA has decided that it will implement its own regulatory scheme for medical devices and will not follow the EU Medical Device Regulation (EU MDR). The EU MDR takes effect in May 2021.
- Medical device manufacturers that want to pace devices on the UK market after January 1, 2021 will need to register with the MHRA.
- Existing CE Marking certificates issued by Notified Bodies will continue to be recognized until June 30, 2023.
- The UK will be issuing its own UKCA (UK Conformity Assessed) mark to replace CE Marking. CE will not be recognized in the EU after June 2023.

# Brexit - What's Next for Medical Device

- If your company does not have a presence in the UK and you sell products there, you will need to appoint a "UK Responsible Person" based in the UK. Despite the name, it's more like a hybrid importer/EC REP role and can be filled by a person or company.
- Your UK Responsible Person must be the one to register your devices with the MHRA but you will only have 4-12 months to register (depends on device classification). You will not need a separate UK Authorized Representative as required under the EU MDR. If you have not already done so, get busy finding your UK Responsible Person as they will also be responsible for registering your devices with the MHRA.
- If you are shipping goods from the UK to the EU by boat, consider making contingency plans as border controls went into effect on January 1, 2021 if all goes as planned. That could slow down shipping until the kinks get worked out. Note that this issue has nothing to do with the EU MDR.

# What has changed? Internal sale

- The MDR also covers internet sales of medical devices and medical devices used for diagnostic or therapeutic services offered at a distance (Article 6).

# Notified Body Audits during COVID-19 quarantine orders and travel restrictions

- Notified bodies may introduce temporary alternative extraordinary measures in place of on-site conformity assessment audits that have been impacted by COVID-19 restrictions and that are within the scope of section 2 above.
- Notified bodies should have documented procedures detailing the alternative temporary measures to be utilized and should define the criteria for implementing such measures (e.g. procedure for “force majeure”).
- The relevant procedures should also take into account the technologies to be used during such audits and also address the impact of the alternative measures on the audit duration.

# Postpones aspects of EU MDR compliance until 2024 for some Class I manufacturers

- This delay, however, applies only to obtaining new CE certificates and NOT to the QMS requirements in the EU MDR.
- This means that a manufacturer of Class I reusable instruments, for example, would have until May 2024 to assemble their technical documentation, but they still have to comply with all QMS requirements – including the implementation of postmarket surveillance, risk management, etc. – before the EU MDR goes into effect in late May 2021.

# Eudamed update: Launch postponed to May 2022

- EUDAMED is the IT system developed by the European Commission to implement Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices.
- EUDAMED is structured around 6 interconnected modules and a public website:
- Actors registration
- UDI/Devices registration
- Notified Bodies and Certificates

# Eudamed update: Launch postponed to May 2022

- Clinical Investigations and performance studies
- Vigilance and post-market surveillance
- Market Surveillance
- On December 1st, 2020 the European Commission made available the Actor registration module. It is the first of six EUDAMED modules.

# Q&A

## JOHN WEBBER

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Principal at MalkanSolutions

## ARMIN BECK

CEO SunTrix Consulting LLC

## GET IN TOUCH:

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