

# Medical Device Regulatory Practices

By Val Theisz

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### **Speaker Biography -**

Ms Valentina Theisz: Val Theisz is a regulatory professional with over fifteen years experience in medical device regulations, Code of Practice; Events;

<http://www.mtaa.org.au/Meetings/PersonBio?ID=1038>

### **Journal of Medical Device Regulation Issue -**

for medical devices, Val Theisz and in the Journal of Medical Device Regulation since taxation is outside the scope of practice for the regulatory

[http://www.globalregulatorypress.com/features/browse\\_issues\\_aug12en.shtml](http://www.globalregulatorypress.com/features/browse_issues_aug12en.shtml)

### **Risk Management for Medical Devices - RAPS -**

Risk Management for Medical Devices Regulatory Exchange: Posted 22 June 2012 By Val Theisz.

<http://www.raps.org/regulatoryDetail.aspx?id=7003>

### **Medical Device Solutions Galway Ireland -**

Medical Device Solutions Galway Ireland is a European based consultancy firm specialising in Validations, Reliability Engineering, Regulatory Compliance,

<http://www.medicaldevicesolutions.ie/>

### **Theisz profiles | LinkedIn -**

Medical Practice Val Theisz Title MSc, RAC (US,EU V&V testing and compliance to EN harmonised and FDA recognised consensus standards for medical devices

<https://www.linkedin.com/pub/dir/+/Theisz/>

### **Forthcoming Biomaterials Books - Taylor & Francis -**

Medical Device Regulatory Practices An International Perspective. By Val Theisz. This book is intended to serve as a reference for professionals in the medical device

<http://www.tandf.net/books/subjects/SCPC1310/forthcoming/>

### **MEDICAL DEVICES AND THE REGULATED PRODUCT -**

August 2012 SPECIAL REPRINT MEDICAL DEVICES AND THE REGULATED PRODUCT SUBMISSION By Val Theisz and Tom Smith Reproduced with the kind permission of Global Regulatory

[http://certificationbody.com.au/documents/JMDRAug2012\\_RPS.pdf](http://certificationbody.com.au/documents/JMDRAug2012_RPS.pdf)

### **Profil som b rjar p Theisz i Sverige | LinkedIn -**

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<http://se.linkedin.com/pub/dir/+/Theisz>

### **Amazon.com: Medical device -**

Successful Launch of New Medical Devices: Medical Device Regulatory Practices Jul 31, 2015. by Val Theisz. Hardcover. \$123.70 \$149.95.

<http://www.amazon.com/s?ie=UTF8&page=1&rh=i%3Aaps%2Ck%3AMedical%20device>

### **US Medical Device Regulations published by US FDA -**

USA Medical Device Regulations Good Reprint Practices - Distribution of Medical Journal Articles for Expedited Access for Premarket Approval Medical Devices:

<http://www.emergogroup.com/resources/regulations-united-states>

### **Amazon.com: medical device: Books -**

Medical Device Development: Regulation and Law Mar 1, Medical Device Regulatory Practices: An International Perspective Aug 6, 2015. by Val Theisz. Hardcover.

<http://www.amazon.com/s?ie=UTF8&page=1&rh=n%3A283155%2Ck%3AMedical%20device>

### **Medicine, Dentistry, Nursing & Allied Health Books -**

Medical Mycology: Current Trends and Future Prospects Medical Device Regulatory Practices: An International Perspective By Val Theisz

[http://www.taylorandfrancis.com/books/subjects/SCME/page\\_422/](http://www.taylorandfrancis.com/books/subjects/SCME/page_422/)

### **Biomedical Engineering Books - Psychology Press -**

Books in the subject of Biomedical Engineering from Psychology Press and the Taylor & Francis Group

<http://www.psypress.com/books/subjects/SCEC02/>

### **Medical Device Regulatory Practices (Hardback) - -**

Medical Device Regulatory Practices By Val Theisz. Pan Overview of risk classification systems and regulatory controls for medical devices and IVDs in

<http://www.tandf.net/books/details/9789814669108/>

### **Theisz Profile Deutschland | LinkedIn -**

Theisz Profile Namenssuche. Vorname; physician at Best Practices, Physician at Inova Health System, Erik Theisz

<http://de.linkedin.com/pub/dir/+/Theisz>

### **Medical Device Regulatory Practices: An -**

Medical Device Regulatory Practices: Val Theisz August 6, 2015 Contains key information about medical device regulations and guidelines in established markets

<https://www.crcpress.com/Medical-Device-Regulatory-Practices/Theisz/9789814669108>

### **Medical Device Regulatory Practices - CRC Press -**

Medical Device Regulatory Practices Medical Device Regulatory Practices. Val Theisz Medical devices,

<https://www.crcpress.com/product/isbn/9789814669108>

### **Staff - Medical Technology Association of -**

What is a medical device? Industry Statistics; Val Theisz, Director Regulatory Affairs; MTAA Staff. Susi Tegen,

<http://www.mtaa.org.au/about-mtaa/staff>

### **Using a medical device that doesn't have 510(k) -**

This FDA requirement applies to medical devices including is manufactured within quality guidelines and best practices. FDA Regulations, Medical Devices

<http://williamlabs.com/blood-banks/using-a-medical-device-that-doesnt-have-510k-clearance-is-like-operating-a-vehicle-without-a-license/>

### **Regulatory Compliance - Medical Device Solutions -**

Regulatory Compliance. We provide expertise on the Risk Management Process for Medical Devices Val Buckley Quality & Regulatory Affairs Director Universal

<http://www.medicaldevicesolutions.ie/services/regulatory-compliance>

### **Val Theisz | LinkedIn -**

helping professionals like Val Theisz discover inside connections to recommended job  
Contact Val directly; Journal of Medical Device Regulation (JMDR)

<http://au.linkedin.com/pub/val-theisz/5/130/919>

### **Medical Device Software Traceability | Valentine -**

(Val) Casey in Medical Education and Software Traceability. Software traceability is central to medical device regulatory compliant traceability practices.

[http://www.academia.edu/1863158/Medical\\_Device\\_Software\\_Traceability](http://www.academia.edu/1863158/Medical_Device_Software_Traceability)

### **Val Theisz | ZoomInfo.com -**

Val Theisz Val www MSc RAC FRAPS, has over fifteen years experience in Regulatory Affairs for medical devices of all risk classifications

<http://www.zoominfo.com/p/Val-Theisz/1780947595>

### **DEPARTMENT OF HEALTH & HUMAN SERVICES Public -**

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, Val Myles . Regulatory Affairs

[http://www.accessdata.fda.gov/cdrh\\_docs/pdf14/K142585.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf14/K142585.pdf)

### **Coping with Defective Software in Medical Devices -**

Medical Devices,Int I an excellent reference for software verification and validation practices ware-based devices in compliance with FDA regulations

<http://www.swqual.com/images/Coping.pdf>

### **Med-Trace - Springer -**

{fergal.mccaffery,val.casey} guidance which the medical device regulations and highly effective and regulatory compliant traceability practices.

[http://link.springer.com/content/pdf/10.1007/978-3-642-21233-8\\_23.pdf](http://link.springer.com/content/pdf/10.1007/978-3-642-21233-8_23.pdf)