EU-US eHealth Marketplace and Conference

To what degree does regulation help/hinder innovation?

Medical Device Suite of Standards
October 22, 2014

OPENSKY PROFESSIONAL SERVICES

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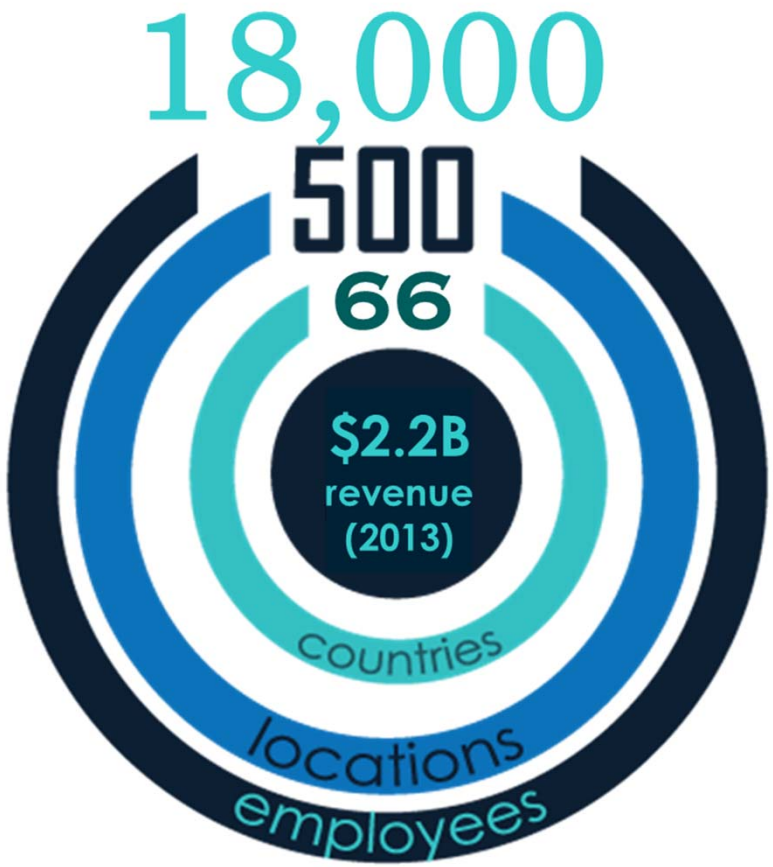
Precisely Right.

GLOBAL NETW


18,000
500
66
$2.2B
revenue
(2013)
countries
locations
employees

WHAT WE DO

OPENSKY PROFESSIONAL SERVICES

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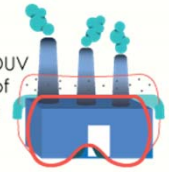
GLOBAL ORIGINS & BACKGROUND

140 YRS OF INNOVATION

1872
Entreprenerus take the initiative & set up the DUV to ensure the safety of their manufacturing plants.



1900
Vehicle inspection & driving license tests.

1918
Activities in the energy & mining sectors.

1926
First material analysis laboratory.

1957
Commitment to environmental protection: Dust register in Cologne.

1969
International product tests & certifications.

1975
Medical work.

2006
Joined the UN Global Compact; Integrated the 2 leading testing institutes in Brazil.

2007
Represented on all continents with the founding of subsidiary in Australia.

2009
With 9 labs in Asia, the USA & Germany, TUV Rheinland further strengthens its world market leadership in the photovoltaic industry.

2010
TÜV Rheinland becomes the second-largest technical service provider in Brazil.

2012
TÜV Rheinland celebrates 140 years. For the first time, more than half of its revenues was achieved outside Germany.

2013
Introduced a new, globally standardized test mark, valid for all services. We provide greater safety & transparency as well as enhanced advertising value.

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PRODUCTS

TUV RHEINLAND's LARGEST and most diverse division

The Products group is our largest division. We check and certify the safety, performance, and quality of technical equipment, medical devices, capital goods, durable goods, and consumer goods. We also offer testing services in compliance with individual criteria, or in line with our renowned TÜV Rheinland standards. Take advantage of our reputation as an independent testing organization for your marketing activities.

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MEDICAL

KEY MARKETS

- Medical Devices (Active/Non-Active)
- Laboratory Products & Equipment
- In-Vitro Diagnostic Devices (IVD)
- Implantable Medical Devices

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Precisely Right.

MEDICAL

EQUIPPED FOR complexity

global network equipped to the highest standards to meet complex scientific & technical requirements

- Product Safety Testing
- Management Systems Certification
- International Product Approvals
- Food & Drug Administration (FDA) Testing
- Product Design Review
- Compatibility Testing
- Restriction of Hazardous Substances
- Component Testing
- Medical Auditing Services
- Electromagnetic Capability (EMC) Testing
- Performance Testing

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Compliance

Approval & Certification

FDA and CE: ‘must-haves’

CSR 820 ➡ MDD ➡ ISO 13485 ➡ 510K

CE 0197

TÜVRheinland® CERTIFIED
www.tuv.com
ID · 0000034860

Market Access

What is typical?

FDA Approval + CE Compliance + Notified Body (NB) Approval + CB Certification (multi-country certification) = Market Access

What is changing?

MDSAP (Medical Device Single Audit Program = Market Access

What is MDSAP?

Market Access

It's a pilot project intended to allow Auditing Organizations (AO's) to conduct a single audit of a Med OEM that will satisfy regulatory authorities participating in the pilot program.

AUSTRALIA, BRAZIL, CANADA & FDA

Currently there are observers to the program: Japan, EU, Russia

TUV Rheinland is applying for the position of AO under this program. The "single" audit performed by the AO will allow OEMs into any of the Four regulated areas.

Market Access

Innovation Pros

- Solving immediate health issues
- Expedient revenue turnover
- Time to Market
- Business ROI

Innovation Cons

- RISK, RISK, RISK!!
- Patient Risk
- Doctor Risk
- Insurance Risk
- Legal Risk
- Business Risk