SGS INVESTOR DAYS 24 – 25 OCTOBER 2013 USA

MEDICAL DEVICES

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Investor Days, 24-25 October 2013

WHEN YOU NEED TO BE SURE

SGS

DEFINITION: MEDICAL DEVICES…

- …are anything that are not either drugs or biologic products
- …usually work physically, while pharmaceutical products usually work chemically or biologically
- …can be therapeutic, diagnostic or something else, whereas pharmaceutical products are usually therapeutic
- Changes can be made to medical devices after they have been placed on the market, resulting in newer, improved versions
- Classifications are based on their intended use, design complexity, their use characteristics, and their potential for harm if misused

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SGS BEHIND MEDICAL DEVICES

- Audit Certification and Verification
- Chemical and Electromagnetic Compatibility (EMC) Testing
- Pharmaceutical Development like Leachables & Extractables
- Project Management for Clinical Trials
- Quality Control Testing
- Training

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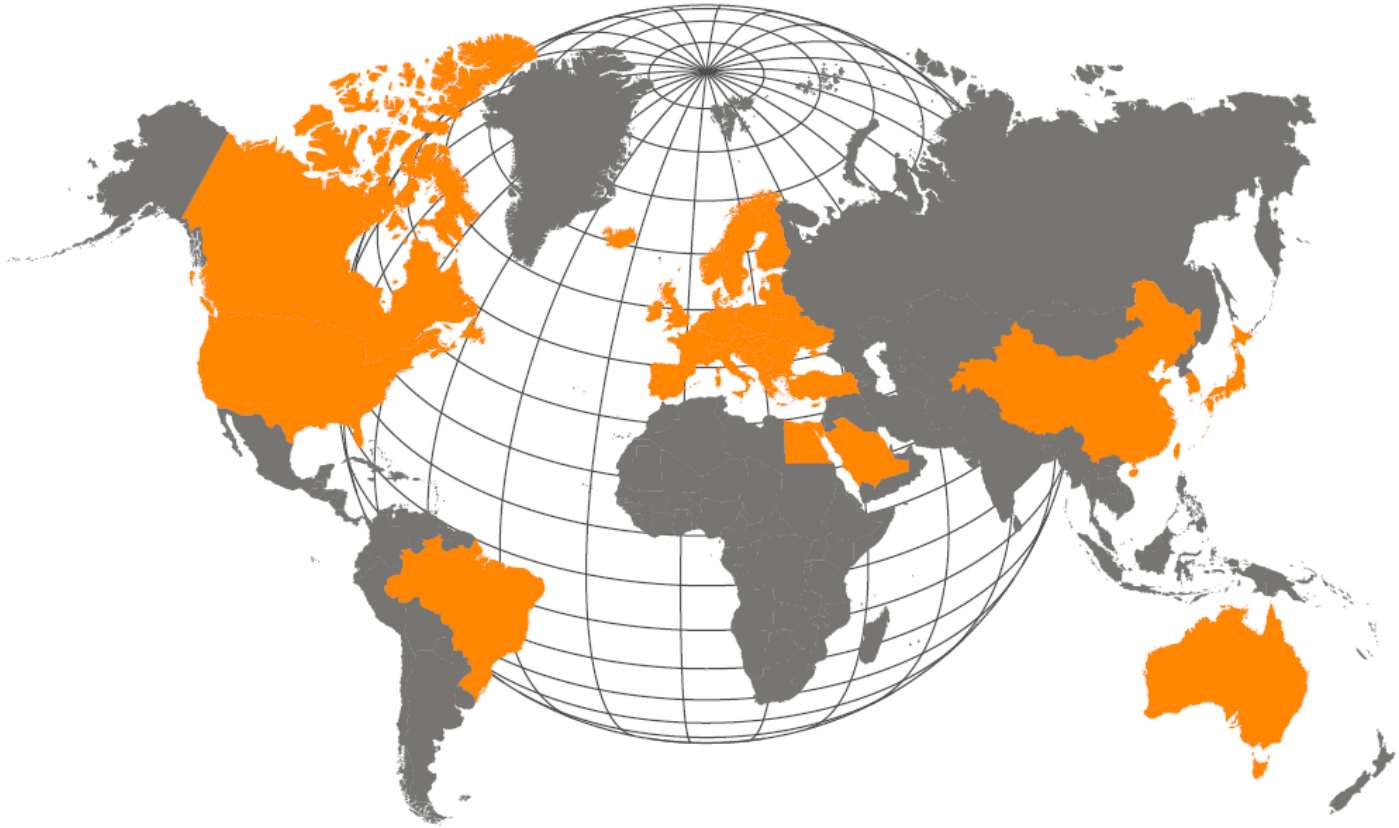

MEDICAL DEVICE REGULATIONS IN THE MAIN GLOBAL MARKETS

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HIGH REGULATIONS
HIGH CHALLENGES

The regulatory aspects of device development are very different than those of drugs

- SGS auditors have extensive knowledge in Medical Device Regulatory aspects

The global regulatory landscape is complex and differ in every regulatory market

- SGS has an international network of experts available in most countries in the world

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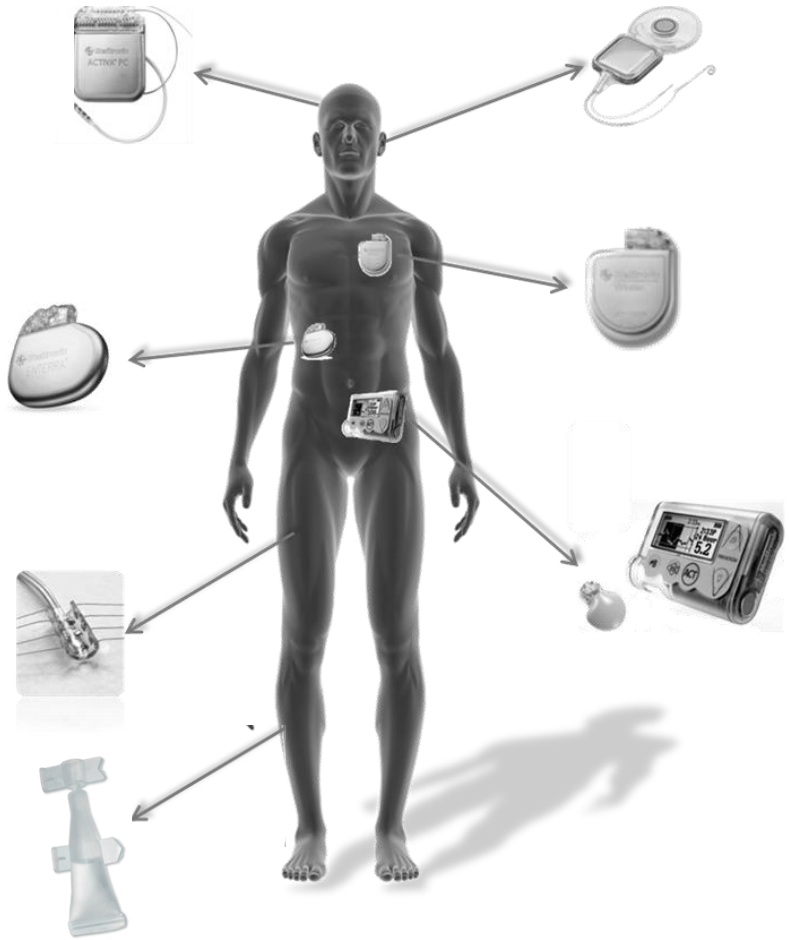
SGS CASE STUDIES

DEEP BRAIN NEUROSTIMULATORS

GASTRIC STIMULATORS

FOOT DROP IMPLANTS

SURGICAL GLUE



COCHLEAR IMPLANTS

CARDIAC DEFIBRILLATORS/ PACEMAKERS

INSULIN PUMPS

CASE STUDY
LIFE SCIENCE SERVICES

GLUBRAN 2
SYNTHETIC SURGICAL GLUE

GLUBRAN® Tiss
SYNTHETIC SKIN ADHESIVE

- Extension of the LSS services portfolio
- Skills based on synergies amongst the LSS network and a new acquisition Sertec Labs in Italy
- Support Medical Devices suppliers in innovation
- Replication of the expertise and experience within the SGS network

SERTEC IS NOW PART OF SGS, THE WORLD'S LEADING INSPECTION, VERIFICATION, TESTING AND CERTIFICATION COMPANY.

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2 QUALITY ASSURANCE SYSTEMS
ISO VERSUS GMP

	ISO	GMP
OBJECTIVES	customer satisfaction	customer protection
BINDING NATURE	voluntary	legally binding
SUPERVISION	neutral institution	health authority
DEGREE OF DETAIL	general	detailed
TYPE OF BUSINESS	all businesses	pharma specific
MAIN EMPHASIS	system related	product related
STANDARDS	own standards	legally set standards

*FDA and GMP Compliance in Quality Assurance Units, 10-11.10.2000, Copenhagen/Denmark
(D. Sullivan:"Maintenance of a Quality Assurance System")

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CASE STUDY
CONSUMER GOODS AND RETAIL

- Safety testing
- EMC testing
- RoHS testing
- Product Certification
- Product Inspection
- Risk Analysis Evaluation
- Design and construction review
- Software
- Usability
- Performance

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CASE STUDY
SYSTEMS AND SERVICES CERTIFICATION

- SGS use their wide range of regulatory approvals to certify products and regulatory quality systems to allow manufacturers access to the European, Japanese, Canadian, Taiwanese, US and Brazilian markets for medical devices as diverse as:
  - Mobile Phone Apps for diagnosis
  - Blood Glucose meters and test strips
  - Hip Implants
  - MRI scanners
  - Coronary stents
  - Scaffolds for promoting bone growth
  - TENS machines for pain relief
  - Toothpastes for acute sensitivity

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CASE STUDY
SYSTEMS AND SERVICES CERTIFICATION

- Canica Design Inc.
- Manufactures sterile wound closure systems
- Certified to ISO 9001, ISO 13485, ISO 13485 under CMDCAS (Canada), and MDD (EU).
- Wanted certification to gain access to international markets and verify that the correct procedures and control systems are in place
- Selected SGS because SGS offers certification to meet all of Canica Design's certification needs.
- Certification provided market access, identified process and product improvements, and provided a system of checks and balances to ensure processes are reliable and repeatable.

"Being certified really helps eliminate trade barriers and has certainly opened doors in most of the countries we've targeted" – Canica President and CEO, Alden Rattew

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Source: http://www.scc.ca/en/news-events/features/2013/how-scc-opens-export-doors-canadian-organizations

SOME GLOBAL REFERENCES

- BAXTER
- BECKTON DICKINSON
- SIEMENS HEALTHCARE
- GENERAL ELECTRIC HEALTHCARE
- JOHNSON & JOHNSON
- PHILIPS HEALTHCARE
- SAMSUNG

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FOR THE COMPLETE PICTURE

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