NSF LAUNCHES COMPREHENSIVE eLEARNING ON MDSAP COUNTRY-SPECIFIC REQUIREMENTS

Are you ready for Medical Device Single Audit Program (MDSAP)? Struggling to find training on all five MDSAP-participating countries' regulatory requirements?

It's finally here! NSF's Medical Device Global Regulatory Requirements training! NSF worked with former regulators and globally recognized experts from each of the five MDSAP-participating countries to bring you this comprehensive online training.

If you've wondered how you'll possibly learn the regulations of countries around the globe, and how you'll ever meet the new competency requirements, our new training courses are just what you need! Choose to complete one or all five of the country modules from our one-stop shop.

Marketing a medical device in a global environment offers many challenges, as regulatory requirements vary widely from one country to another. Bringing a product to market in multiple countries requires understanding the differences and knowing how to comply with regulations and procedures. This training series provides comprehensive instruction on the individual country's regulatory structure and the requirements necessary to bring a product to market in that jurisdiction…and to keep it there!

What is MDSAP? This program allows recognized third-party auditing organizations (AOs) to conduct a single audit that will satisfy the relevant regulatory requirements of all participating regulatory authorities. These authorities include Australia's Therapeutic Goods Administration (TGA), Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), Health Canada, Japan's Pharmaceuticals and Medical Devices Agency (PMDA) and the United States Food and Drug Administration (FDA).

MDSAP audits save time and money by replacing multiple lengthy audits, allowing less interruptions in manufacturing schedules. In addition, Canada has deemed MDSAP certification mandatory for marketing as of January 1, 2019. With the increase in utilization of MDSAP, and the time constraint of Canada's looming deadline, it's essential that manufacturers and auditors understand the regulatory requirements of participating countries to ensure readiness for the MDSAP certification audit.

What is the training format? This series features country-specific requirements for Australia, Brazil, Canada, Japan and the United States. These online courses offer highly interactive instruction on each jurisdiction's **legal and regulatory** framework, **premarket pathways** and requirements, and **postmarket regulations**. They also highlight specific country requirements that must be considered in conjunction with **MDSAP audits**.

Each highly interactive and engaging course in the series takes approximately 90–120 minutes to complete. Each course includes knowledge checks and final assessments, resulting in a *Certificate of Successful Completion*, demonstrating objective evidence of competency. This objective evidence is now a critical component of your company's training files, as required under the new ISO 13485:2016.

Why NSF courses? NSF's eLearning program offers you the flexibility to learn at your own pace, on your own schedule. Our flexible online modules are fun, interactive and available 24 hours a day, seven days a week. No worries about scheduling conflicts or costly travel expenses; we offer all your learning needs with the click of your mouse.

To develop these eLearning modules, we tapped into the knowledge of medical device experts from all over the world, with extensive regulatory, industry and notified body experience. The courses were then designed by skilled and licensed educators, making our courses a one-of-a-kind experience.

NSF International's medical device team understands our customers' needs and we're committed to providing the highest quality services. The depth and breadth of our global experts, along with our long-standing relationships in the international standards arena, means that we keep abreast of global trends and pending revisions. So, rest assured that in the constantly changing regulatory landscape, we will provide consistent training tools to keep you informed and to satisfy competency requirements.

For more information on the eLearning program, visit **www.nsf.org/info/md-elearning**

NSF INTERNATIONAL | MEDICAL DEVICES

2001 Pennsylvania Avenue NW, Suite 950, Washington, DC 20006 USA.

T 1 202-822-1850 | **E** medicaldevices@nsf.org | **www.nsf.org** | **www.nsfmedicaldevices.org**