TC001606A

foi teleconferences

Teleconference Course Materials

You may duplicate this for each person attending the conference.

Getting Your Medical Device Approved in Brazil: What To Do & When To Do It

by a Panel of Experts

Date: **Wednesday, February 8, 2012**

Time:

1:00pm – 2:30pm	**Eastern Standard Time** (GMT/UT 1800)
12:00pm – 1:30pm	Central Time
11:00am – 12:30pm	Mountain Time
10:00am – 11:30am	Pacific Time

Call-In: **Dial 1-888-848-0354 approximately 10-15 minutes prior to the start time.**
When prompted, enter the PIN code followed by the # key: 2439731#
Outside the U.S. & Canada, you will receive special instructions by email.
If you become disconnected and cannot reconnect through the number above, you can also call in on +1-801-853-0800.

At the conclusion of the conference, an audio file will be made available for order. Attendees receive a special reduced price of $225.
To order go to *www.foiservices.com/braz9731* or call 301-975-9400.

Important Notice

The information provided in this course by the instructor is his/her personal opinion and does not necessarily represent the opinions of FOI, Inc. or its staff. Companies relying on the information do so at their own risk and assume the risk and any subsequent liability that results from relying on the information.
The information provided does not constitute legal advice.

Produced by: **FOI Services, Inc.**
704 Quince Orchard Road • Suite 275
Gaithersburg MD 20878-1770 USA
Phone: 1-800-654-1147 or +1-301-975-9400
Fax: 301-975-0702
Email: infofoi@foiservices.com
www.foiservices.com

Getting Your Medical Device Approved in Brazil: What To Do & When To Do It

Nicohl Wilding
Senior Auditor and Regulatory Subject Matter Expert
Regulatory Compliance Associates Inc.

Chris Henza
Regulatory Affairs Specialist
Regulatory Compliance Associates Inc.

Eliana Silva de Moreas
Latin America Regulatory Affairs Specialist
Ph.D., Health Law - Paris VII University
President, Brazilian Regulatory Professional Society

An FOI Services Teleconference • Wednesday, February 8, 2012

Medical Device Regulation in Brazil

Eliana Silva de Moreas

Latin America Regulatory Affairs Specialist
Ph.D., Health Law - Paris VII University
President, Brazilian Regulatory Professional Society

Topics

- Understanding the Brazil RA Legislation
- Learning how to facilitate the RA process
- Learning how to improve the RA environment in Brazil

Administrative Law Systems & Procedures

- The structure (federal, state, municipal)
- Centralized vs. decentralized
- Language: Use of Portuguese is mandatory for all official documents in Brazil
- Considerations for documents; e.g., copies, fees, standards, technical information

Requirements

- Specific agreements
- Trademark registrations
- Patent registrations
- Technical reports and the disclosure of trade secrets
- Is there a system to protect confidential information?

Observations

- **Distributors** must register their establishment with ANVISA (federal permit) and Local Sanitary Surveillance Authority.

- **Device Manufacturers** must have a GMP audit approved by ANVISA.

Understanding

- Local presence or distributor?
- Registration, Notification or Exemption?
- Classification (Risk I, II, III, IV)?

Market Access Requirements

You can only market a medical device in Brazil under certain conditions:

- Setting up a company in Brazil, or
- Through a Brazilian distributor

Note

All apparatuses, instruments and accessories used for medical, odontological and similar purposes can be manufactured or imported for delivery for consumption and/or displayed for sale only after approval through the registration or exemption process.

Requirements

- Products in Class I and II: Notification (RDC n.24/09)

- Products in Class I, II and III and IV: Registration

Basic Content Requirements for an Application for Imported Medical Devices

a) Application form from the Agency
b) Bank slip confirming payment of the public tax
c) Trade permit from state authority for the distributor's office
d) Same document from federal authority
e) Document issued by the appropriate entity showing the technical responsibility
f) Label sample for the product
g) Label sample of the instructions, cautions and directions for use
h) Copy of legal document in which the manufacturer authorizes its distributor to trade and distribute its product
i) Registration (or certificate of free sale) of the product in the country of origin
j) Technical report

Technical Report

- **Detailed description** of the medical product, including the bases for its functioning and action, its content or composition, when applicable, as well as a list of the accessories that are intended to form an integral part of the product

- **Indication, purpose or use**

- **Precautions, constraints, warnings, special measures** and additional information on the use of the medical product, as well as its storage and transportation

- **Forms of presentation** of the medical product

- **Flowchart** demonstrating the **stages of the medical product, with a brief description of each stage of the process** through to the finished product

- **Description of the efficacy, safety and security** of the medical product in compliance with the ANVISA Regulations

Label Information

- The manufacturer and importer name
- Information strictly necessary for the user to identify the medical product and the contents of the package
- When applicable, the word “sterile”
- The code number for the batch, preceded by the word “batch” or the serial number as applicable
- The fabrication and expiry date, as applicable
- When applicable, the indication that the medical product is for use once only
- Special storage, conservation and/or handling conditions for the medical product
- Instructions for use for the medical product
- All warnings and/or precautions to be taken
- When applicable, the sterilization method
- The name of the technical expert in charge; must be legally qualified for this function
- Registration of the medical product, preceded by the identification acronym: ANVISA

Information Required

- The information on the label and in the instructions for use should be written in **Portuguese**.

- All medical products **should include instructions** for use in their **packaging**. On an exceptional basis, these instructions may not be included in the packaging for products ranked under Classes I and II.

- The information required for the correct, safe use of the medical products should **always appear on the product itself**.

- **If it is not possible** to pack each unit individually, the information describing correct, safe use should be included **with the instructions for use accompanying one or more medical products**.

Economic Information Report

The Economic Assessment Unit/Regulation (NUREM) requires the following information:

a) The price of the product in other countries

b) The potential number of patients for whom the product is intended

c) The intended price for the Brazilian market with a breakdown of its tax load

d) A detailed sales proposal for the product, including planned outlays on sales drives, publicity and advertising

e) A list of the substitute products currently on the market, including the price of each product

Guide for the Report

1.2. Company name

1.3. Information on the product

1.3.1 Risk rating

1.3.2 Technical name

1.3.3. Commercial name and/or model

1.3.4. Detailed description of the product

1.4 Reason for the Application - Registration or Revalidation of Registration

2. Economic Data

2.1 Price of the product in other countries

2.1.1 Factory price, broken out into taxes and distribution margin, with the necessary proof of source in the country of origin and the provenance of product, and also in the following countries, if applicable

2.2 Potential number of patients per year for whom the product is intended

2.2.1. Potential number of patients using the product or who will undergo tests, indicating the sources for this estimate and the respective calculation methodology

FAQs

- Re-used product?
- Traceability label?
- Time frame?
- How many distributors?
- Certification for electrical equipment?
- Premarket notification?
- Electronic process?

Getting Your Medical Device Approved in Brazil: Lessons Learned

Nicohl Wilding
Senior Auditor and Regulatory Subject Matter Expert
Regulatory Compliance Associates Inc.

Chris Henza
Regulatory Affairs Specialist
Regulatory Compliance Associates Inc.

Registration Process

What do I need to know right now?

Do I Need to Register My Device?

- Yes. All classes of medical devices require registration.
- The Registration Authority is **ANVISA** - The National Health Surveillance Agency.
- www.anvisa.gov.br

What is the Cost of Registration?

- Cost is determined by size of the company and its annual revenue (article 46, RDC/ANVISA n. 222/06 and Federal Act 9.841/99)

- Average cost is about US$8,000 per submission

How Long Does it Take to Register a Product?

- Per Federal Law n. 6360/76, the timeframe for product registration is 90 days. However, my experience is that the time from submission to approval is approximately 9 - 12 months.

- The clock doesn't start until the Ministry of Health receives the documentation.

- Each time the Ministry of Health asks a question or requests further information, the clock stops until that piece of information is received by the Ministry.

- Postage time (for receipt of documentation or final approval/ clearance) is not included.

Does the Registration Expire?

- Yes. The registration is good for 5 years.

- The renewal does requires a complete re-submission, but the re-submission could take less time for approval than the original.

What are the Language Requirements for a Labeling & Submission Package?

- Product labels must be in Brazilian Portuguese.
- The Submission Package must be translated to Brazilian Portuguese.
- Translations can be done by the in-country representative or distributor or a translation house that provides a certificate of accuracy.

Basic Requirements

- Legal documents
- Certificate to Foreign Government (CFG) or Certificate of Free Sale (CFS)
- Power of Attorney (POA) for distributor in Brazilian Portuguese
- CFG/CFS and POA documents require legalization from the Brazilian consulate or embassy

Basic Requirements

- Site documents
- ISO Certificate
- Manufacturing flow chart

Basic Requirements

- Product documents
  - Finished product drawing
  - List of components (i.e., BOM)
  - Packaging materials
  - Labels
  - Instructions for use
  - Product brochure
  - Product testing

Basic Requirements

- Testing documents
  - Release test (representative report)
  - Functional testing
  - Sterilization parameters
  - Biocompatibility test reports
  - Electrical safety test certificate
  - EMC test report or certificate

Do I Need to Register My Manufacturing Facility?

- No. However, a GMP audit must be conducted by ANVISA prior to your device submission.

- Part of the registration process includes inviting ANVISA to conduct an audit:
  - Not all items are audited
  - Electrical items are always audited
  - The audit is often outsourced to an ANVISA-approved auditor

The Audit

- INMETRO Certification for Electromedical Devices
  - **Safety:** Testing according to IEC 60601-1 and IEC 60601-2-X
  - **EMC:** Testing according to IEC 60601-1-2
  - **Software:** Validation according to IEC 60601-1-4
  - **Routine tests:** 100% of products tested according to routine tests described in IEC 60601
  - **Audit:** Factory has to audited annually by registered auditors
  - **Test reports**: Must not be not older than 5 years
  - **Test laboratory:** Test lab must be accredited by Accreditation Body of ILAC

Are There Additional Requirements Beyond Registrations?

- Yes - there are Customs import requirements
  - Invoice is compared to the officially published device approval
  - Items always checked:
    - Device name and part number
    - Manufacturer name

Are There Post-Market Requirements?

- Yes
  - Adverse Events
  - Recalls and Corrections
  - Device Tracking

Changes to Products

Distributors should be informed of any change.

If I Make a Change to My Device Do I Need to Amend My Registration?

- Yes - a new registration is required for any significant change

- Other changes require notification or an amendment to the registration

Representative

Your relationship with your representative is a major commitment.

Do I Need an In-Country Representative?

- Yes - a Brazilian representative is required.
- The registration holder is the in-country representative. However, the manufacturer's name is also listed on the registration.
- Registrations can be transferred between distribution partners.

How Do I Locate a Distributor or In-Country Representative?

- There are many distributors and companies offering to serve as your representative.
- Finding a reputable distributor is not always easy.
- The best way I have found is to ask around at meetings and in online forums.
  - For example, the Regulatory Affairs Professional Society (RAPS) Annual Meeting is one good place to pose questions to others who have experience selling medical devices in Brazil.

How Can I Check Distributor References?

- This is another complicated task.

- Again, the best practice is to solicit opinions from other professionals.
  - Consider asking questions via online forums and in-person meetings such as those hosted by RAPS and other industry organizations.

What are the Key Provisions of the Distributor Contract?

- Confidentiality agreement
- Notification of any complaints or adverse events
- Providing complete package of everything submitted to ANVISA
- Assistance with translations
- Assistance with any recalls or advisory notices
- Termination of the contract
- Assistance with transfer of license upon termination of agreement
- Sales price

How Difficult is it to Change Distributors?

- This can be difficult because the distributor's name is on the license.

- Changing the distributor name can often take as long as the initial registration.

How Political is the Registration Process in Brazil?

- At this time there do not seem to be any specific political issues surrounding the registration process.

What is the Process for Importation of Sample Devices for Evaluation?

- Importation requirements are detailed in RDC 350/05 Chapter II

- Samples can be imported prior to registration approval
  - They must be clearly labeled as samples not for use

How Far in Advance Should I Request an Audit?

- Once a request is placed it can take 9 months or longer for ANVISA to perform the GMP audit.

- ANVISA is in the process of approving Notified Bodies to conduct audits on their behalf.

Questions?

All questions are welcome.
Anyone in your group may ask questions. To protect your privacy, questions will be announced using only the first name of the person reported to the operator at dial-in. Please avoid using a speakerphone while asking your question.

If you think of a question later or prefer to discuss an issue privately, you are invited to contact the speakers directly:

Eliana Silva de Moreas: eliana@silvademoraes.com.br [Web: www.abpvs.com.br]

Nicohl Wilding: n.wilding@rcainc.com & **Chris Henza** : c.henza@rcainc.com
Regulatory Compliance Associates Inc. [+1-262-842-1250; Web: www.rcainc.com]

We value your feedback.
Please complete and return the evaluation on the next page of this handout to be entered into a prize drawing for a $100 amazon.com gift card and/or arrange to receive a certificate verifying your participation in the 1.5 contact hours of this educational session.

Handouts & audio files.
These slides are online at www.foiservices.com/braz9731. The site also includes instructions for ordering an audio file of this presentation at a 50% discount.

Training Evaluation Form

TC001606

Getting Your Medical Device Approved in Brazil: What To Do & When To Do It
February 8, 2012 — Presented by a Panel of Experts

Win a $100 Amazon.com Gift Certificate from FOI!

Just complete this form and fax it to +1-301-975-0702 by February 15, 2012
and you will be entered in a drawing for an Amazon.com Gift Certificate

Please indicate your primary job responsibility (circle one):

Regulatory Affairs QA/QC Statistics Medical Writing Electronic Submissions General Management
Other (please specify):_____

Please rate various aspects of this course
(1 = Poor; 2=Fair; 3=Good; 4=Very Good; 5=Excellent – please circle your answers)

What is your overall rating of the course?	1	2	3	4	5
How do you rate the content of the course?	1	2	3	4	5
Were course materials clear and understandable?	1	2	3	4	5
Was the length of the course adequate to cover the content?	1	2	3	4	5
Were the instructors knowledgeable about the subject matter? *(please note any comments about specific instructors below)*	1	2	3	4	5
How would you rate the instructors overall?	1	2	3	4	5

Other comments:

Please feel free to comment on any aspect of this course, including the speakers, content, and technical arrangements:

_____

_____

_____

_____

_____

_____

☐ **Check here to receive a Certification of Attendance verifying your 1.5 training contact hours for this educational session.** Please provide your legibly printed name with your signature next to it, email address, and fax this form to the number below. Your certificate will be emailed to you.

By providing the information below and faxing this page to +1-301-975-0702 by Wednesday, February 15, 2012 you will be entered in a drawing for a $100 Amazon.com Gift Certificate from FOI.

Your Name: _____

Company Name: _____

Email Address: _____