BPS
Bio Pharmaceutical Solutions
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Due Diligence: The Critical Role that Regulatory Affairs Play!

Is your company involved in the following?

- Licence acquisition
- Licence divestment
- Company acquisition

The knowledge and skills of Regulatory Affairs professionals are important and integral elements of any pharmaceutical business. There are many situations where these talents are needed by other parts of the business. One of these is in the area of Regulatory Due Diligence. A systematic and thorough Due Diligence process is vital in maintaining and expanding on your business capabilities, which is top of mind for senior pharmaceutical executives.

Who should attend?

- Regulatory Affairs
- Business Development
- Finance / Legal
- Other Senior Executives
- Other departments (Logistics, Quality Assurance, Medical Information, Drug Safety, etc)

What will the participants learn?

The Regulatory Affairs professional must interact with a large variety of people. Understanding and addressing their needs can be challenging, as is communicating the needs of their own Regulatory Department and that of the Therapeutic Goods Administration. This course will empower Regulatory Affairs professionals to contribute significantly to the due diligence process, to the increased benefit of their business, and their working relationships. In addition to this, the course is also useful for other areas of the business in understanding how Regulatory Affairs can help them.

Course Overview

This course will work through the most common scenarios such as licence acquisition or divestment and company take over.
Participants will gain an in-depth understanding of the Due Diligence process including:

- Performing a Gap analysis of the data
- Rate limiting headlines: What are they and how will they affect the project?
- Estimating the work required to obtain a dossier fit for the TGA
- Assessing and communicating the likelihood of approval
- Best case and Worst case scenarios
- Communication strategies internally and externally
- Timing of submission
- Likelihood and timing of approval

Participants will be encouraged to develop an understanding of the background to the project so that they can most effectively contribute to it, by asking questions such as:

- Why is this of interest to the company?
- What company information is already known and available?
- How important is this to the company?
- What is the overseas Regulatory Status?
- What are the differences in EU and USA dossier requirements, which may impact the data package?
- What is their Good Manufacturing Practice status?
- What other departments are involved and how should we communicate with them?
- How will the data be transferred and what sort of regulatory support will be available?

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Course Outcome

At the conclusion of the program, participants should have gained an understanding of how Regulatory Affairs can significantly contribute to the Due Diligence process in areas such as:

- Licence acquisition
- Licence divestment
- Company acquisition
- Selecting new suppliers

With this understanding, participants will be able to develop or refine internal procedures to assist with the company's next Due Diligence project.

Course Duration

Initially Bio Pharmaceutical Solutions would undertake training needs analysis over 4 - 8 hours which will ensure that any information presented is contextualised to company in-house terminology and is consistent with company Standard Operating Procedures. This would also be used to identify and develop scenarios for action based learning during the program.

The training program would be delivered over a total of 1.5 days, with the first day spent covering the regulations and theory component with several small scenario based exercises to reinforce the learning's.

A further 0.5 day follow would be scheduled for several weeks after this session and involves a more complex scenario and presentation by participants.