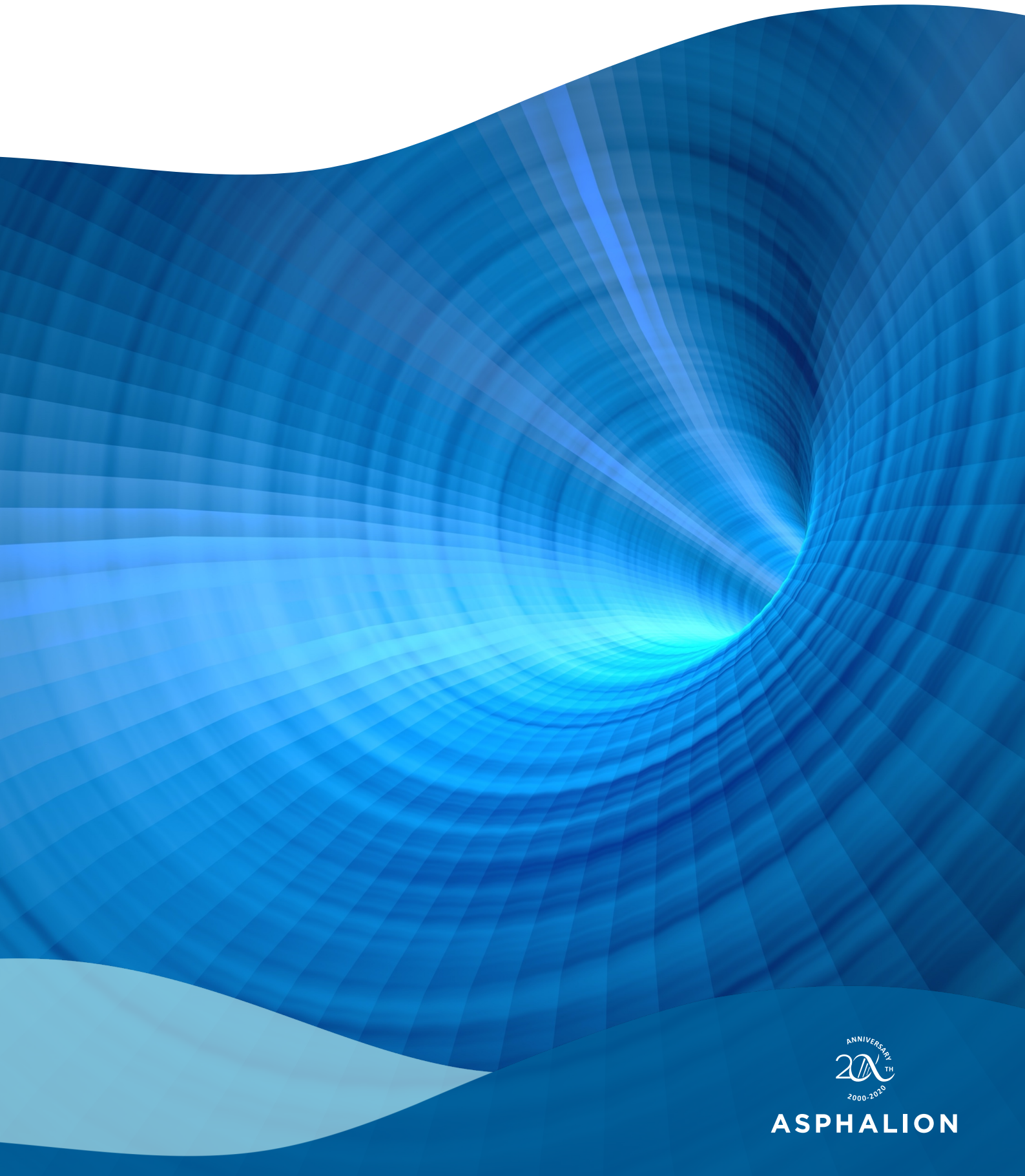
Implementing a RIMS

Phase 1: RIMS selection



ASPHALION

Introduction

From not so long ago, the pharmaceutical industry has been moving **towards a greater information control** by handling data related to the registration records of its medicines.

The EMA's drive towards IDMP (implementation expected February, 2022) and NVR, the New Veterinary Medicines Regulation (Regulation (EU) 2019/6) legislation, which implementation is expected for January, 2022) are being key factors.

Because of this, **the need arises to manage and trace a large amount of information** in the most precise and accurate possible way in order to make it immediately available.

Furthermore, we are moving towards a situation where decision making, strategy creation and analysing different situations are **based on data**. Because of this, there is an increasing need for companies to implement tools such as a **RIMS.**

It is a complex process indeed, but Asphalion has accumulated many years of experience, which is why **we know in detail the different key aspects in the different phases of implementation of a RIMS** that can be distinguished:

1. RIMS selection
2. RIMS configuration
3. Mapping, collecting and cleaning data
4. Data import / migrations
5. Validations
6. Trainings and Work Instructions

Phase 1: RIMS Selection

The first step is the **selection of the RIMS** that best suits your company. There are different vendors in the market and each one of their tools have a different functionality.

It is advisable to **align the internal requirements** with the functionalities offered by the different RIMS.

At Asphalion we have participated in **numerous RFIs** and have experience in preparing them. Also, we know most of the vendors on the market, so that **we can put the customer in touch** with each of them.

With all the available information, you have to **make the decision** about the most suitable RIMS for your business.

Here are the **features that a RIMS must have** to fulfil its purpose:

What should an effective RIMS look like?

- Enables to quickly and accurately identify **product information** requested by regulatory agencies
- Collects product information under the **eCTD specification**
- Takes into account the **variation of products** in the different agencies when creating a record
- Correctly **manages file changes** and revisions, as well as product updates
- **Generates documentation** subject to be submitted according with standards
- **Tracks all** presentations and publications
- **Reduces times** to issue submission to Regulatory agencies
- Allows a **clear monitoring** from original submission during product life cycle
- **Adapts to company needs** in terms of data volume and size to be managed
- Complies with **Regulatory requirements**

Doubts that might arise when choosing a RIMS

We have compiled a number of questions that usually arise in all companies when choosing a RIMS, according to several criteria:

1. Company structure

How is your company's **organizational structure defined?** It is essential to know this information, as this will define a requirement. **Types of registrations** you are interested in: **EU, FDA, ROW,** etc.

2. Architecture

Deploying to a cloud-based system has its advantages and drawbacks. If you choose such a system, you should keep in mind that accesses will depend on **good internet connection** and you will probably have to review your **company's security policies**. That is why you need to involve the IT department. We have to ask ourselves what situation we are starting from. If you already have a **document manager system,** this can be reused; should you have the **entire structure in folders, Excel documents, Word and/or PDF, or a database itself,** this fact is decisive when migrating data to a RIMS.

3. Functionalities

Although most RIMS on the market offer the same modules, each company manages it differently. The **different modules** that each RIMS have should be very **well identified.** Here's a list:

- Product database
- Document manager
- Quality module (usually included in document manager)
- Manager for submitting information to agencies (submissions & publishing)
- Planning and monitoring of activities
- Pharmacovigilance and surveillance for medical devices
- Clinic module

4. Integration and interoperability

Isolated information systems lose productivity: at this point, we will have to **carry out an analysis** to ensure that our future RIMS has **good interoperability**.

5. Compliance

Another important aspect to consider is whether a **RIMS is prepared for new regulations (IDMP/UPD).** In addition, you'll need to take a deep look at whether you want to submit to agencies through a Gateway, or by using a specific module to do so. There are RIMS that have their own specific module

6. Reporting & training

There is a little-mentioned feature about RIMS, but not less important, which is **reporting and possible integrations with BI systems**.

Another important aspect to keep in mind is knowing what type of support you will receive once the RIMS has been implemented.

Asphalion Expertise

Asphalion is an international Scientific and Regulatory Affairs consultancy company, with offices in Barcelona, Madrid, Munich and London. Founded in 2000, Asphalion has grown consistently, and now employs more than 100 team members from 12 different nationalities with backgrounds in Pharmacy, Chemistry, Biology, Biochemistry, Biotechnology, Medicine, Engineering, and Information Technology.

Asphalion collaborates with Pharmaceutical, Biotechnological and Medical Technology organizations facilitating product development and regulatory affairs solutions for their projects.

Our services range from early development throughout the registration, until marketing and post-commercialization phases of your product.

If you have any questions do not hesitate to contact us!

info@asphalion.com
www.asphalion.com