CEDAR BAY

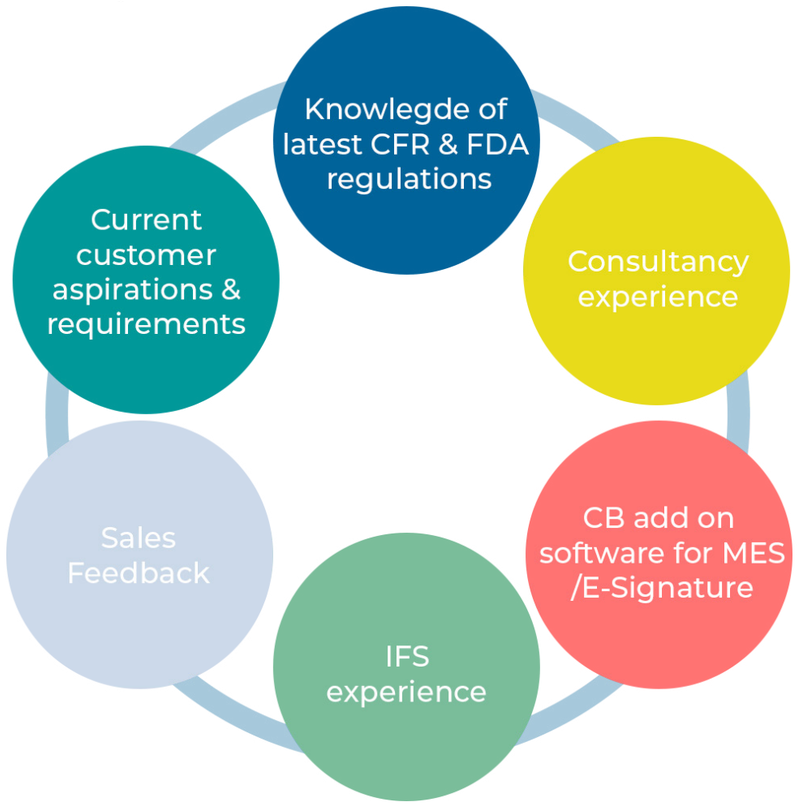
CEDAR BAY LIFE SCIENCES ACCELERATOR

SUMMARY

Life Sciences companies can find it extremely difficult to implement new software and processes due to the strict validation and protocols that they operate within. Cedar Bay has worked with many Life Sciences customers over the years and we have brought together our knowledge of Life Sciences businesses, Validation processes, CFR Part 11 and GMP. This knowledge alongside our IFS expertise has enabled us to build an Accelerator to improve the time to benefit and ultimately the quality of our customer's IFS implementations.

THE BACKGROUND

In many implementations the validation and regulatory requirements are not built into the main project plan for the ERP implementation, and it is seen as a secondary time-consuming task. With the Cedar Bay Accelerator, we aim to help companies reduce this time and integrate the regulatory requirements within the main project elements. The diagram below shows how we've brought together our experience to create the Accelator shown on the right-hand side.



PROJECT MANAGEMENT

Every business is different, and no-one can provide an 'out of the box' solution to validation, but we can use template test plans to speed up the implementation and reduce the efforts required by our customers. Our Accelerator is delivered with a level of project management, this sets out the Validation plan template based on our existing structures of documents. It assesses the implementation scope and processes for the customer and identifies the work to be completed.

The project management time also includes time to review the requirements for GMP and CFR Part 11 to understand if any areas of the IFS solution will pose a risk, and therefore will need work on security or custom events to prevent certain actions without full controls.

THE VALIDATION TEMPLATES

Using the IFS Scope Tool, we have reviewed the key processes in IFS that directly affect product quality and delivery, and we have categorised these alongside the risk they pose to the product integrity. For the key processes we have created a set of user requirement specifications and test plans to cover the Operational Qualifications (OQ) and Performance Qualification (PQ). This provides a quick start to the validation processes as they are pre-built test plans which saves the customer a vast amount of time and effort.

THE CFR PART 11 EXAMPLES

As part of the validation plan there may be CFR Part 11 and GMP items that need to be enhanced from IFS core functionality. As part of the accelerator, we have created a series of CFR Part 11 example enhancements to provide additional control. Much of what is required in an implementation is covered directly by IFS security and controls, but inevitably there are areas where not enough control can be provided. We have created some examples of solutions to IFS transactions where extra controls are needed, these are used as the basis of the training we provide to explain how these are implemented in our customers systems. These can then be delivered by the customer's IT team or by Cedar Bay.

Validation Plan Template	Validation Plan Template User Requirement Specification QR Plans · PQ Plans
Part 11 and GMP Samples	Series of working code examples to provide additional controls, approval loops & logging
Project Management	Work with customers implementation team to develop validation plan template to complete validation & identify Part 11 risks
Technical Consultancy	Work with customers technical team to train on extensibility techniques to add additional controls and logging

OTHER KEY FUNCTIONALITY

Cedar Bay has worked with many companies within the Life Sciences sector and have experience of other areas that are often key to the successful business improvement projects.

Falsified Medicines Directive 2011/62/EU

We have provided customers with solutions to allow communication with the Avarto platform for drug validation, which is built into the standard IFS processes for in-bound and out-bound material movements.

Automated Testing

We have methods of automating testing, this not only key to our customers to speed up the initial validation process, but more importantly to test new releases as they are deployed to the IFS solution. With the advent of the IFS Evergreen approach where patches are delivered en masse customers need to be able to verify that they do not affect their validated IFS system.

Dispensing

Often manufacturers will need dispensing solutions and Cedar Bay can provide this functionality directly by integrating IFS to scales for real time feedback and control of the products being issued.

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