

# Project Management



## **Managing pharmaceutical, medical device and food manufacturing facility projects to ensure regulatory compliance**

Sometimes, companies just don't have the resources or knowledge to manage a plant upgrade. This is particularly the case when TGA/FDA or Medsafe compliance is a critical factor.

PharmOut offers project management services to help you get production up and running and comply with the relevant regulations. Our extensive experience in the pharmaceutical and food industries will ensure that things like "develop maintenance life plans for machinery" are on the project plan. Under-estimating the required validation effort is another common project management mistake.

PharmOut can help you at any point in your project. Including:

- Writing the user requirements specification
- Project planning
- Project management
- Validation and Quality plans
- Project post mortem studies

PharmOut consultants use the Good Automated Manufacturing Practice (GAMP) 'V' model for project management. This model is now widely accepted within the pharmaceutical and medical device industries for validation and project management.

PharmOut does not supply engineering or trade services. Instead, we will manage the project using your onsite services. Alternatively, we can help with selecting vendors for the various components of the project. Our independence ensures that the best vendor is selected for each part of the project.

To talk to us about managing a project, please visit [pharmout.net](http://pharmout.net) for contact details.

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[www.pharmout.net](http://www.pharmout.net)