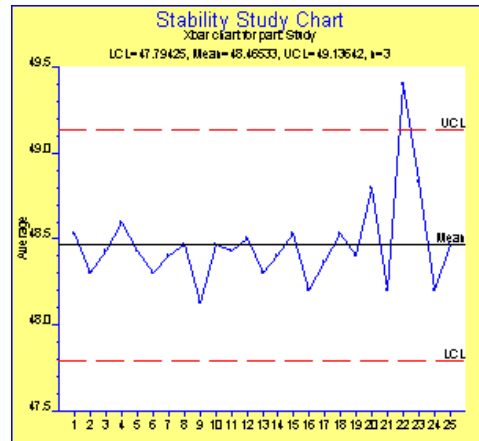


Guidelines for Stability studies

Objective:

Shelf-life and stability studies are costly and time-consuming to carry out. It is important to know the key elements in setting up efficient studies.



Moreover the data collected are often censored and require adapted statistical analysis tools.

The course provides you with a description of this unique type of data and analysis, what tools can and cannot be used and why, how to best analyze life data and how to properly interpret and communicate the results obtained.

Special emphasis is put on the practical application of the techniques for shelf-life studies by means of examples and discussions.

At GMP Services, we don't just consider what we need to say, but also how we are going to say it. This way we ensure that our courses are interesting and interactive. And because we are willing to spend some time with you discussing your products and your process, it can be customised and specific.

Suitable for:

All employees involved in stability programmes from analysts to regulatory affairs personnel.

Course Details:

Basic Course (1 Day)

- Critical elements of a Stability Programme
- The regulations governing stability
- The documentation required - SOP's; Protocols; Reports
- Stability samples & storage conditions



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- The qualification, management & monitoring of stability chambers
- Accelerated, Intermediate & Long Term studies
- Stability Methods & Validation
- Results - evaluation & reporting
- Failure investigation - OOT & OOS
- Statistical Analysis & Trending
- Reduced testing: Bracketing And Matrixing
- Stability reports
- Common errors and citations in stability programmes.

A multiple-choice questionnaire will be used to evaluate the training. This is an Irish Medicine Board requirement.

On completion of training, we will provide the company with an 'Inspectors package', which will describe the course content, the tutors, the evaluation results, etc. This will allow for an easy, clear evaluation of the training by any external audit team.

Tutor:

Our GMP training courses are presented by Valerie Mulholland. Valerie is a Senior Consultant in GMP and particularly in FDA requirements. Valerie has over 15 years experience in both the medical device and finished pharmaceutical industries. Valerie has worked in the area of Quality Management for most of her career.

Valerie is a popular tutor and presents her courses in an entertaining manner.

Benefits:

On completion of this course, attendees will have a good understanding of stability requirements and the regulations.



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Details:

Course cost is available on request. This cost includes the provision of all training materials and course manuals. A session can accommodate up to 15 employees.

The cost does not include tutors accommodation or travelling expenses. Travel expenses will be charged at 63c/ mile. Training facilities will be provided at the company's expense.

Further Information:

We would be delighted to make an appointment to discuss your particular training requirements.

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