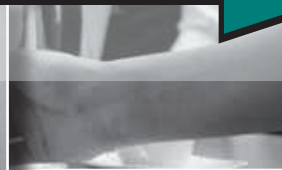
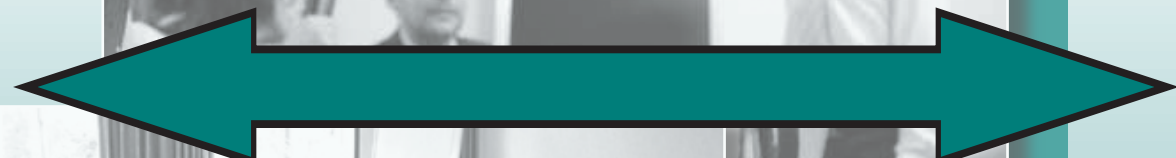


PHARMACEUTICAL CONSULTANCY SERVICES

Internal Training

(prospectus 2009/2010)



INTRODUCTION

PCS has organised (external) training courses since 1990; in particular, the GMP training aimed at middle management in the pharmaceutical industry has become an established event in the Netherlands. Companies have regularly requested PCS to perform in-house, custom-made training courses covering a wide range of subjects, in response to specific requirements.

In recent years, PCS has invested considerably in creating and developing new training courses; several years ago, we established a cooperation with the renowned British pharmaceutical engineering company Honeyman Group Limited, with the purpose of bundling know-how and expertise. As a result, we are able to offer you a broad range of in-house training courses. The advantages of considering in-house training and an overview of our current internal training programme are presented below.

WHEN IS INTERNAL TRAINING USEFUL?

Number of participants

If a larger number of employees should be trained, it can be financially advantageous to organise an in-house training. These can be held locally, so that as a rule, no additional travel or subsistence costs are incurred by the participants.

Standardisation within the company

An internal training course that includes personnel from different departments can foster not only a good grasp of the regulations and improve understanding of why certain processes/procedures are conducted in a specific way, but can also help towards creating better mutual understanding and promote the standardisation of processes within the company.

Own Rules, Own Product, Own Requirements

A further advantage of internal training courses is that the programme, training content, workshops, exercises and methodology can be adapted to suit the specific needs of your company. Made-to-measure training can be provided by incorporating your product and your procedures into the programme, so that the participants receive specific input that relates directly to their own tasks, responsibilities and daily experience.



WHAT CAN PCS OFFER?

Professional trainers; different training styles

PCS provides suitably educated and professional trainers who are all experts in the setup, development, supervision and performance of training. In order to enhance the efficacy of in-house courses, PCS use various training methods; in addition to the transfer of knowledge via (interactive) lectures, intensive use is also made of questionnaires, practical exercises, workshops and photo presentations.

Up to date know-how

PCS trainers do not lecture full-time. Next to participating in training courses, they are also active within the pharmaceutical industry, where they bear (shared) responsibility for the performance of audits, interim management, project supervision, consultancy etc. As a result, the trainers are fully informed about new regulations and problems confronting their clients. This means that the expertise and know-how of trainers is constantly being enhanced and renewed; this allows PCS to offer practical “hands-on” training, rather than simply providing theoretical knowledge.

Qualification Programme

PCS also offer the possibility of conducting an effectivity test upon completion of a training course, in order to assess the improvement in knowledge of the participants. Upon completing the course, the participants will receive a certificate which states the subject and date of the training. This can, if required, be linked to the result of the effectivity test.



INTERNAL TRAINING SUBJECTS

Auditing:

- Internal and external auditing
- Advanced auditing techniques
- FDA inspection preparations
- Auditing QC laboratories
- Auditing aseptic processes
- Auditing API/excipient suppliers
- Auditing computerised systems

Quality systems:

- Documentation system/management
- Setting up a CAPA system
- Deviation/CAPA management
- Change Control
- Risk Management
- Third party contracting
- Contract production
- Contract analysis
- Training systems
- Train the trainer
- Supplier Qualification
- PQR (Product Quality Review)

Engineering:

- GEP (Good Engineering Practice)
- Equipment management
- Water systems
- Self-inspection techniques
- Equipment maintenance
- Equipment calibration
- Equipment validation
- Validation Master Plan
- Sterilisation Processes
- Sterilisation and validation - advanced
- Bio-indicators
- Implementation of ASTM 2500 (risk-based qualification)
- Equipment control during the life cycle

Computerised systems:

- Introductory course on computerised systems
- GAMP 5

GMP:

- Introduction to GMP (for ancillary personnel)
- GMP for operators
- GMP for middle management
- Annual GMP update
- Good Distribution Practices
- GMP for biotechnological products

QC laboratories:

- GcLP (Good Control Laboratory Practice)
- Laboratory equipment management
- OOS (out of specification)
- Reagents and standards
- Validation of analytical methods
- Validation of microbiological methods
- Stability testing
- Transfer of analytical methods
- Handling raw data
- Implementation of LIMS
- Spread sheet validation

Production processes:

- Packaging
- Aseptic production
- Environmental Monitoring
- Disinfection and sterilisation
- Process validation
- Risk analysis of production processes
- Hygiene for production personnel
- Microbiology for non-microbiologists
- Cleaning validation
- HACCP
- FMEA
- Principles of contamination control



The above represents a selection of courses that PCS can deliver. Additional subjects are available upon request.

PCS Internal Training

REQUEST FOR INFORMATION


If you would like further information about our internal training courses or other PCS services, please do not hesitate to get in touch either via e-mail, telephone, fax or post. You may also choose to complete the form provided below and forward this to us by fax or post.


ORGANISATION

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 www.pcs-nl.com

WHAT DOES PCS DO?

Pharmaceutical Consultancy Services is an established, independent consulting group that provides specialised consulting and training services to the pharmaceutical, medical devices and related health care industries with respect to the development and application of current industrial good manufacturing practices, in order to meet regulatory requirements.

Founded in 1990, it has grown steadily, with affiliated offices in Germany. Our constant and intensive contacts within the industry and with government and health organisations, both at home and abroad, ensures that clients receive the most up-to-date information and cost-effective solutions to any regulatory issues. PCS operates globally and can count amongst its client base some of the leading multinational pharmaceutical organisations. This extensive customer base allows us to provide clients with both benchmarking and “best current practice” advice, while our extensive network of associates ensures that PCS can provide a specialised project team to meet all GMP/ QA/ Validation/ Training and Regulatory requirements, in order to assist clients in achieving compliance with current Good Manufacturing Practices.

REQUEST FORM FOR INTERNAL TRAINING

Name

Company

Street/P.O. Box

Postcode..... Town

Telephone number Fax number

Email address

Date Signature

*Please return to us by fax or post;
alternatively you may email us directly at info@pcs-nl.com or via the website, www.pcs-nl.com.*