Objective of this seminar
Following the seminar the participants will have a clear understanding of the cleaning process and the critical issues. The participant is able to create a cleaning SOP and to perform a cleaning validation.

Course No. 3-VCP-1011

www.huettlin.com
The cleaning process in the pharmaceutical industry is as important as the production process itself. For this reason the seminar range „EXPERT OF SOLIDS“ certificated by HÜTTLIN is starting with the cleaning process and its corresponding validation.

On the first day the participants will be introduced to the cleaning process and critical parameters will be explained. Directly at the production size high shear mixer and fluid bed system, critical spots will be identified and a cleaning SOP for the case study product will be created during a workshop.

On the second day the focus will be on the cleaning validation of the case study product. The participant will be taught about cleaning validation and a cleaning validation plan will be created.

**Day One**  
**October 12, 2011**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>08.10 – 08.20</td>
<td>Registration</td>
</tr>
</tbody>
</table>
| 08.20 – 08.30 | **Introduction**  
  Dr. M. Knöll (Hüttlin)                                                                 |
| 08.30 – 09.15 | **Background of cleaning**  
  Dr. A. Knöll (F. Hoffmann-La Roche AG)                                                      |
| 09.15 – 10.15 | **Regulatory environment**  
  Dr. A. Knöll (F. Hoffmann-La Roche AG)                                                      |
| 10.15 – 10.30 | **Coffee Break**                                                                            |
| 10.30 – 11.30 | **How detergents work**  
  B. Grabe (Ecolab)                                                                           |
| 11.30 – 12.00 | **Selection of cleaning detergents**  
  B. Grabe (Ecolab)                                                                           |
| 12.00 – 13.00 | **Lunch Break**                                                                             |
| 13.00 – 13.45 | **Case Study with**  
  F. Hoffmann-La Roche AG / Hüttlin
  generation of a cleaning SOP - Part I                                                      |
| 13.45 – 14.15 | **Practical evaluation of two different cleaning systems**  
  B. Grabe (Ecolab)  
  Dr. M. Knöll (Hüttlin)                                                                      |
| 14.15 – 14.30 | **Coffee Break**                                                                            |
| 14.30 – 15.30 | **Cleaning concept of Hüttlin**  
  U. Schmidt (Hüttlin)                                                                        |
<p>| 15.30 – 15.45 | <strong>Coffee Break</strong>                                                                            |</p>
<table>
<thead>
<tr>
<th>Time</th>
<th>Day One: October 12, 2011</th>
</tr>
</thead>
</table>
| 15.45 – 17.00 | **SOP - Part II** F. Hoffmann-La Roche AG / Hüttlin  
On this basis of part I a cleaning SOP will be generated. |
| 17.00 – 17.20 | **Wrap-up and inspections of the equipment** All                                               |

<table>
<thead>
<tr>
<th>Time</th>
<th>Day Two: October 13, 2011</th>
</tr>
</thead>
</table>
| 09.00 – 10.00 | **Analytical methods for APIs, detergents and contaminants, sampling and recoveries included** Dr. W. Woiwode (TECPharm)  
Back to the roots: TOC-, UV- and HPLC-determination are going to be covered in more detail. In combination with pH, conductivity, and, if desired, microbiology most of the common residues will be detected, if adequate sampling procedures are available. |
| 10.00 – 10.15 | **Coffee Break**                                                                          |
| 10.15 – 12.00 | **Cleaning Validation – How to do it** Dr. A. Kööl (F. Hoffmann-La Roche AG)  
On the basis of an example the concept of cleaning assessment/validation a cleaning SOP will be provided. The lesson begins with the necessary documentation before the assessment starts and goes through the calculation of the residue limits and finishes with the documentation of a successful cleaning validation procedure. |
| 12.00 – 13.00 | **Lunch Break**                                                                           |
| 13.00 – 13.30 | **Cleaning Validation for Detergents** B. Grabe (Ecolab)  
Presentation of the software  
Definition of limits  
Maintaining the standards of a good Cleaning Validation, cleaning agents have to fulfil many requirements.  
The P3-cosa-range of Ecolab complies with most of these requirements. Actual documents are summarized in a web based software. The software will be introduced and contains a calculator for limits of detection. The participant has the possibility to get this software in his own country. |
| 13.30 – 16.00 | First group: Dr. A. Kööl (F. Hoffmann-La Roche AG)  
Generation of a cleaning validation plan and report of the case study  
Second group: Dr. W. Woiwode (TECPharm)  
Sampling techniques, rinses and swabs in real time  
The participants will be divided into several groups. One group will learn from a practice session. They will create a cleaning validation plan and report of the case study.  
In the other group the sampling will be performed by rinsing and swabbing contaminated surfaces. Advantages of different tools will be discussed. Real time measurement by UV spectrophotometry will be demonstrated.  
The groups will rotate into each exercise session so that everybody can benefit from the whole program. |
| 16.00 – 17.00 | **Presentation of the results and open questions** All                                      |

**Who should attend?**

Professionals engaged in development or production of solid dosage forms.
"EXPERT OF SOLIDS" AND "MASTER OF SOLIDS" CERTIFICATED BY HÜTTLIN

Description

The "EXPERT OF SOLIDS" (four seminars, certificated by HÜTTLIN) is the preliminary stage of the "MASTER OF SOLIDS" (additional two seminars, certificated by HÜTTLIN).

All aspects of development and production of solid dosage forms will be highlighted from the basis of granulation, via the experimental design to the compression of the tablets. A "MASTER OF SOLIDS" will gain detailed knowledge in manufacturing solid dosage forms.

Individual courses on "EXPERT OF SOLIDS" can be taken.
Please sign up to the seminar by e-mail.

Surname  First Name  Title

Position  Department

Company  Industrial Sector

Street / P.O. Box

Postcode  Location, Country

Phone  Fax

E-mail

Date, Signature

☐ Please reserve ______ single / double room(s) for ______ night / nights from _________ to _________.

☐ Please organize a taxi transfer from the airport to the hotel / to Hüttlin and back. (Flight information will be forwarded to Hüttlin as soon as possible.)

☐ I will arrive by car.

The reservations are limited. Reservation is confirmed when we receive full payment.

Price for Seminar

984€ (excl. VAT), 10% reduction for participants from a previous course
(Inclusive: lunches and beverages during the seminar and dinner on the first day)

As soon as we receive your registration form we will send an invoice to you with our banking details and more detailed information on the seminar.
YOUR SPEAKERS

• **Dr. Marcus Knöll**
  After finishing her PhD (University of Frankfurt) she started in 1999 with Boehringer Ingelheim Pharma GmbH & Co. KG and led the GMP Service within the Pharma Production/Quality Assurance. She was responsible for quality of the media supply, deviation management, SOP’s, GMP-Training, inspections, production masterdata, etc. From 2005-2007 she headed the department Compliance/Validation (Pharmaplan Engineering AG, Basel) before starting as head of Qualification Validation Monitoring within Global Development Formulations (F. Hoffmann-La Roche, Basel). Responsibilities today are the qualification of equipment for production of solids, liquids (parenterals), the validation of cleaning/sterilization processes, monitoring of production rooms and the ownership of databases.

• **Dr. Antje Knöll**
  After finishing her PhD (University of Frankfurt) she started in 1999 with Boehringer Ingelheim Pharma GmbH & Co. KG and led the GMP Service within the Pharma Production/Quality Assurance. She was responsible for quality of the media supply, deviation management, SOP’s, GMP-Training, inspections, production masterdata, etc. From 2005-2007 she headed the department Compliance/Validation (Pharmaplan Engineering AG, Basel) before starting as head of Qualification Validation Monitoring within Global Development Formulations (F. Hoffmann-La Roche, Basel). Responsibilities today are the qualification of equipment for production of solids, liquids (parenterals), the validation of cleaning/sterilization processes, monitoring of production rooms and the ownership of databases.

• **Burkhard Grabe**
  Born in Lüdinghausen/Germany, in 1966. After obtaining his High School Diploma he studied chemistry in Konstanz/Germany (1988-1994). As a Territory Manager from 1994-2002 he had extensive experience in the use of cleaning agents in the food industry. He has been working for Ecolab, Inc. since 2002 as Territory Manager and as Key Account Manager. He is in direct contact with pharmaceutical companies and provides valuable advice in terms of cleaning. He has specialized in cleaning surfaces, where validation is essential.

• **Uwe Schmidt**
  After his degree in Process Engineering at FH Konstanz/Germany (1992), he was until 1997 Project Engineer in R&D at EKATO UNIMIX GmbH, Bremen and EKATO Rühr- und Mischtechnik GmbH, Schopfheim. Responsible for innovation projects and customer trials in the R&D laboratory. Until 2004 he was Project Manager R&D and responsible for a new founded business unit for solid processing. Taking up the cooperation with Hüttlin GmbH in 2000 and responsible for the development of the high shear mixer/granulator HMG. He was Managing Director of EKATO SOLIDMIX GmbH and EKATO UNIMIX GmbH – later merged into EKATO SYSTEMS GmbH. Since 2006 he is Head of Project Management and R&D at Hüttlin GmbH, Schopfheim/Germany.

• **Dr. Wolfgang Woiwode**
  After his study in Chemistry at the University of Tübingen/Germany he completed the Ph. D in Organic Chemistry and Peptide Synthesis in 1977. Until 1979 he worked as Head of the Laboratory in the Institute for Occupational and Environmental Health. From 1980-1985 he was Head of the Product Control Department and Deputy of the QC-Director at A. Nattermann & Cie./Germany and until 1992 QC-Director of Bristol Arzneimittel/Germany. Dr. Wolfgang Woiwode was Technical Director of BioChem, Labor für biologische und chemische Analytik GmbH, Karlsruhe/Germany (1993-1997). Since 1997 he is General Manager of TECHPharm GmbH, Bruchsal/Germany. He has special expertise in quality control and manufacture of starting materials and pharmaceuticals, process validation, cleaning validation, facility management; audits of manufacturers of starting materials, packaging components, intermediates and finished pharmaceuticals; consultancy with related action programs and improvements in the same areas.