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Sartorius, an internationally leading laboratory and process technology provider covering the segments of biotechnology and mechatronics



UNC Pembroke Regional
Center for Economic,
Community & Professional
Development Project BIO
NSF Grant # 0332650

REGISTRATION INFORMATION

**SEMINAR COST: \$125 BY MAY 11, 2007
\$150 AFTER MAY 11, 2007**

Registration includes continental breakfast, snack and drinks as well as seminar hand-outs & materials

To register via e-mail: len.holmes@uncp.edu

Name: _____
Organization: _____
E-mail address: _____
Telephone Number: _____

PAYMENT METHOD (MASTER CARD/VISA/CHECK)

Card Holders Name: _____
Credit Card #: _____
Expiration Date: _____
Signature: _____

FAX REGISTRATION FORM TO:
Attn: LaVonne Wilkerson – 910-775-4005

MAKE CHECKS PAYABLE TO:
The University of North Carolina at Pembroke (UNCP)

**Payments will be accepted on the day of this event;
however, seating is limited.**

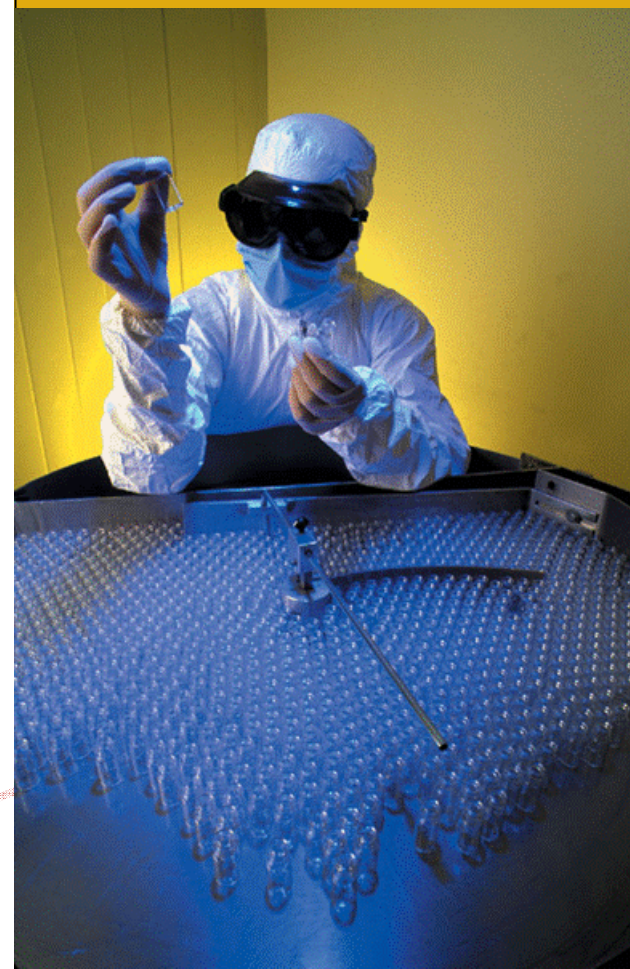
**Questions/Comments: Contact LaVonne at (910)
775-4014 or LaVonne.wilkerson@uncp.edu**

Cleaning Validation Choices & 483's Filter & Polymer Extractables

May 22, 2007



NC STATE UNIVERSITY



PRESENTERS

Frank S. Kohn, Ph.D.

SESSION ONE

Dr. Frank S Kohn is the president of FSK Associates Inc. and he will shed light on cleaning validation and the consequences of failing to meet regulatory expectations



for cleaning procedures. The possibilities of cross contamination due to inexact cleaning procedures have become a growing concern and focus of the FDA, causing pharmaceutical, biotech and bio-pharmaceutical companies to recognize the significance of cleaning validation and the need for knowledge of standard cleaning processes.

A. Mark Trotter, MS, MBA

SESSION TWO

Mr. Trotter is Product Manager, Technical Training Services for Sartorius Corporation. He has over 20 years experience working in the pharmaceutical and bioscience industries. Mr. Trotter

has presented numerous seminars and training courses on membrane filtration and aseptic processing topics. Mr. Trotter is a member of ISPE, PDA, and ASM.

CLEANING VALIDATION CHOICES & 483'S FILTER & POLYMER EXTRACTABLES

SEMINAR DESCRIPTION

SESSION ONE

CLEANING VALIDATION CHOICES & 483'S

- ☼ How to select cleaning technologies, cleaning agents, analytical methods, residue challenges, grouping strategies and validation programs.
- ☼ Better understanding of current cleaning validation is-
- ☼ Hands on opportunity to practice developing a cleaning protocol.

SESSION TWO

FILTER & POLYMER EXTRACTABLES

- ☼ Definition of Polymeric Extractables and Leachables in Pharmaceutical Processes.
- ☼ How to determine the requirements for qualification and quantification of extractable analysis. What are the current industry and regulatory expectations and trends for extractable analysis?
- ☼ Where and When in the Manufacturing process Extractables should be of concern and the process parameters and formulation characteristics: dosage, toxicity, surface areas, time, temperature, solvent systems.



AGENDA

8:30-8:45 Meet & Greet

SESSION ONE

8:45 Cleaning Validation Choices & 483's

9:45 Better Understanding of Current Cleaning Validation issues & Sampling plans

10:30 Break

10:45 Case Study

12:00 Lunch (**on your own**)

SESSION TWO

1:30 Defining Polymeric extractables & leachables

2:30 Break

3:00 Qualification & Quantification of extractable analysis

4:00 Case Study

WHERE

North Carolina State University
Centennial Campus

Larry K. Monteith Research Center, Room 246
(www.ncsu.edu/campus_map/centennial.htm)