STUDENT TRAINING

PEOPLE RESOURCE AVAILABILITY

PPAR Meeting
October 13, 2003

NEED TO DEFINE PAT

- ***RAW MATERIAL***
- ***API***
- ***MIXING***
- ***FORMULATION***
- ***PRODUCT TESTING***

AREAS OF PAT

- ***SENSORS***
- ***DATA HANDLING***
- ***SYSTEMS***

  SAMPLING, DETECTION, DATA HANDLING
- ***UNIT OPERATIONS***

LEVEL OF TRAINING

- ***GRADUATE LEVEL***
  - ***CHEMISTRY (PROCESS AND ANALYTICAL)***
  - ***PHARMA ENGINEERING***

- ***UNDERGRADUATE***
  - ***ENGINEERING (ChE, EE, PHARMA ENG)***

CONSORTIA

- ***CAMP***
- ***CPAC***
- ***CPACT***
- ***MCEC***
- ***PURDUE (IUCRC)***
- ***UM***
- ***McMASTER***
- ***COPENHAGEN, KOLDING***
- ***ETC.***

CPAC Activities

- Semiannual Sponsor Meetings
- Graduate Education
- Summer Institute
- Technical Workshops
- Visiting Scientist Program
- PAT
- IFPAC, Pittcon, ISA

PROGRAMS IN CONSORTIA

- *FUNDED RESEARCH PROJECTS*
- *STUDENTS*
- *POST DOCS*
- *VISITING SCIENTISTS*
- *FOCUSED PROJECTS*

- *EMERGING TECHNOLOGIES*
- *INITIATIVES*

PAT Training Program
for Selected FDA Reviewers and Inspectors
(PATRIOT)

- Program (CAMP, CPAC, MCEC)
  - Session #1 (didactic)
  - Session #2 (practicum – laboratory exposure and industrial site visits)
  - Session #3 (didactic)

- Expectations
  - Technical & Regulatory Leadership
  - Team concept - Integrated systems thinking
  - Continuing education (future industry involvement)

TRAINEE RESPONSE

- **HIGH INTEREST LEVEL**
- **VERY ENTHUSIASTIC ABOUT PAT**
- **QUITE COMPETENT**
- **MOTIVATED TO LEARN**

- *Many questions and much discussion*

RESOURCE POOL

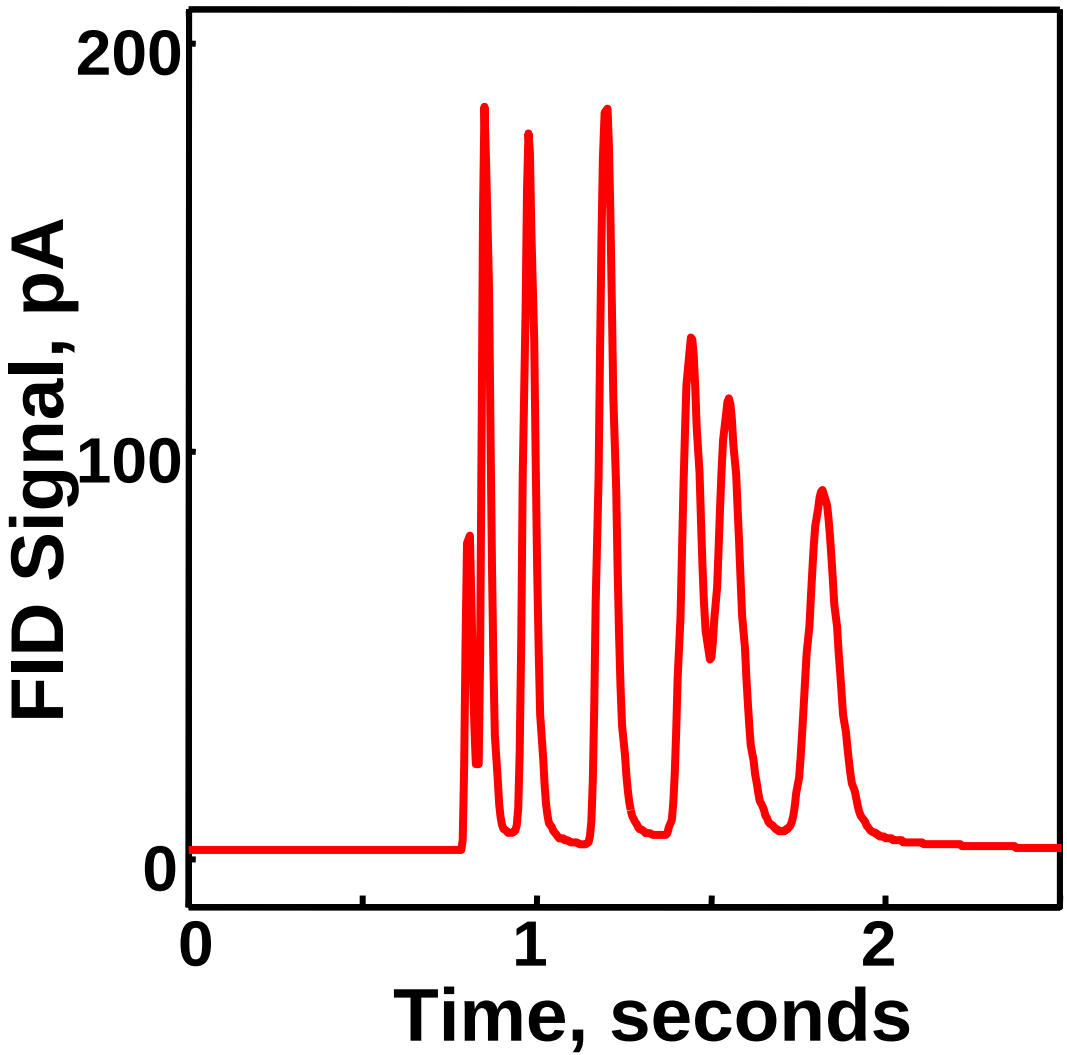
- *DOWNSIZED FROM OTHER INDUSTRIES*
- *ORGANIZED OUTSIDE GROUPS*
  - *PROBLEM SOLVING, PROJECT INVOLVEMENT*
  - *NEED TO ASSESS INTEREST LEVEL*
- *CONSULTANTS*
- *CONSORTIA*

MICRO-SENSORS

- ***MINIATURE LAB INSTRUMENTS***
- ***SMALL PHYSICAL SENSORS***
- ***BIO-SENSORS***
- ***NANO TECHNOLOGY***
  - ***Moisture, GC, particle related***

- DRIVERS (DHS, DARPA, Semi-Conductor, Telecommuncation, ETC.)

High-Speed chromatogram using a Monolayer Protected Nanoparticle column



Elution Order

1. Methyl ethyl ketone
2. Benzene
3. Octane
4. Chlorobenzene
5. Anisole
6. 3-Octanone
7. Decane

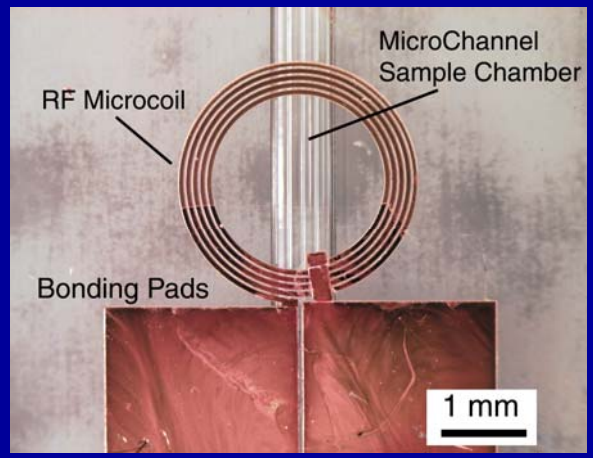
R. Synovec CPAC UW

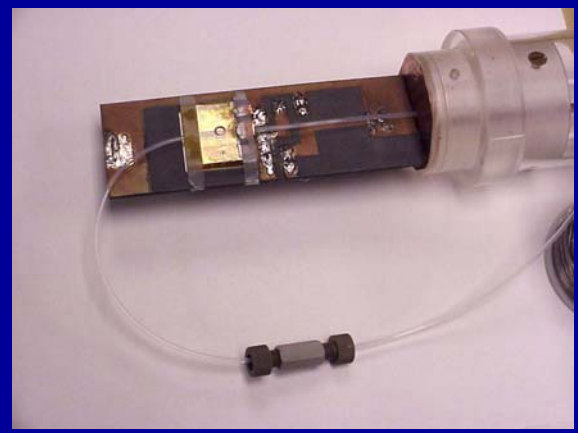
Development of a Micro NMR System

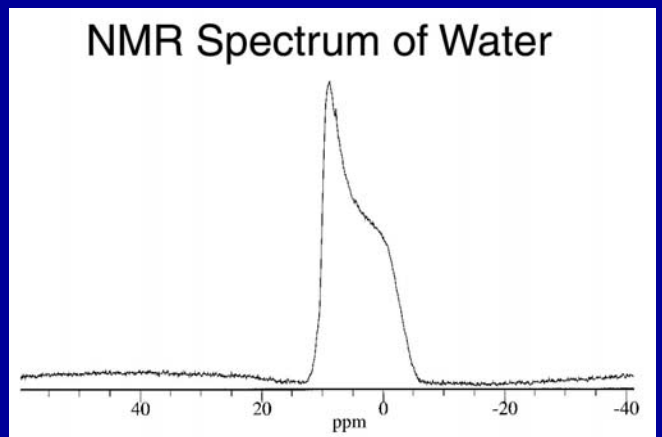
CPAC UCDAVIS

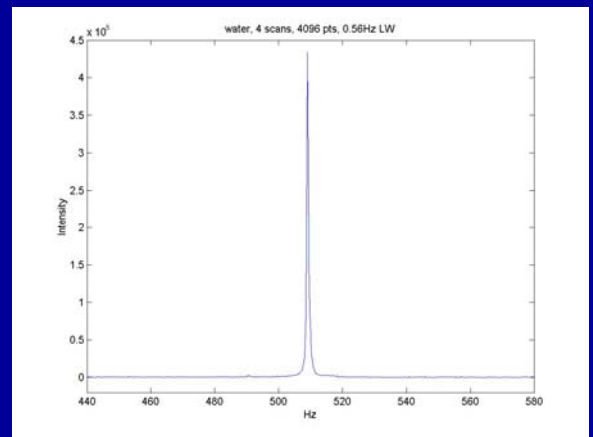
NMR spectrum of a 3 micro liter water sample using a RF micro coil

Initial Results









INITIATIVES

- ***NeSSI (New Sampling and Sensor Initiative)***
- ***FERMI***
- ***HTE (Micro-Reactors and Micro-Sensors)***
- ***Chemometrics for On-Line Process Analysis (COPA)***

NeSSI

Picture courtesy Swagelok®

The NeSSI Platform Will Also Become the Base for a Micro-Analytical Lab

NMR
MS
NIR
RAMAN
LC
GC
FIA
Particle Size
Viscosity
Moisture
Conductivity
Mass Flow
Etc.

NeSSI with an Array of Micro-Analytical Techniques will Impact:

- **Process Control**
- **Process Optimization**