



Research Versus Manufacturing
14th DEA Pharmaceutical
Conference
Portland, OR

Susan M. Carr
Deputy Chief

Drug Enforcement Administration
Office of Diversion Control
Drug and Chemical Evaluation Section

Research vs. Manufacturing

A close-up photograph of a person in a white lab coat performing a laboratory procedure. The person's hands are visible, one holding a glass vial and the other holding a beaker. The vial is tilted, and a clear liquid is being poured into the beaker. The background is slightly blurred, showing more of the lab coat and a patterned tie.

- Research and Manufacturing are designated as independent activities for which separate registrations are required with the DEA
- 21 CFR 1301.13 (e) (1) describes specific coincident activities for which separate registrations are not required

Researcher Coincident Activities

21 CFR 1301.13(e)(1)

A hand in a black glove is pouring a blue liquid from a beaker into a graduated cylinder. The graduated cylinder has markings at 50, 100, 150, and 200. The background is white.

- Schedule I:
 - manufacture or import substance for which registration was issued and set forth in protocol (21 CFR 1301.18)
 - distribute to persons registered to conduct research or chemical analysis with such substance

Researcher Coincident Activities

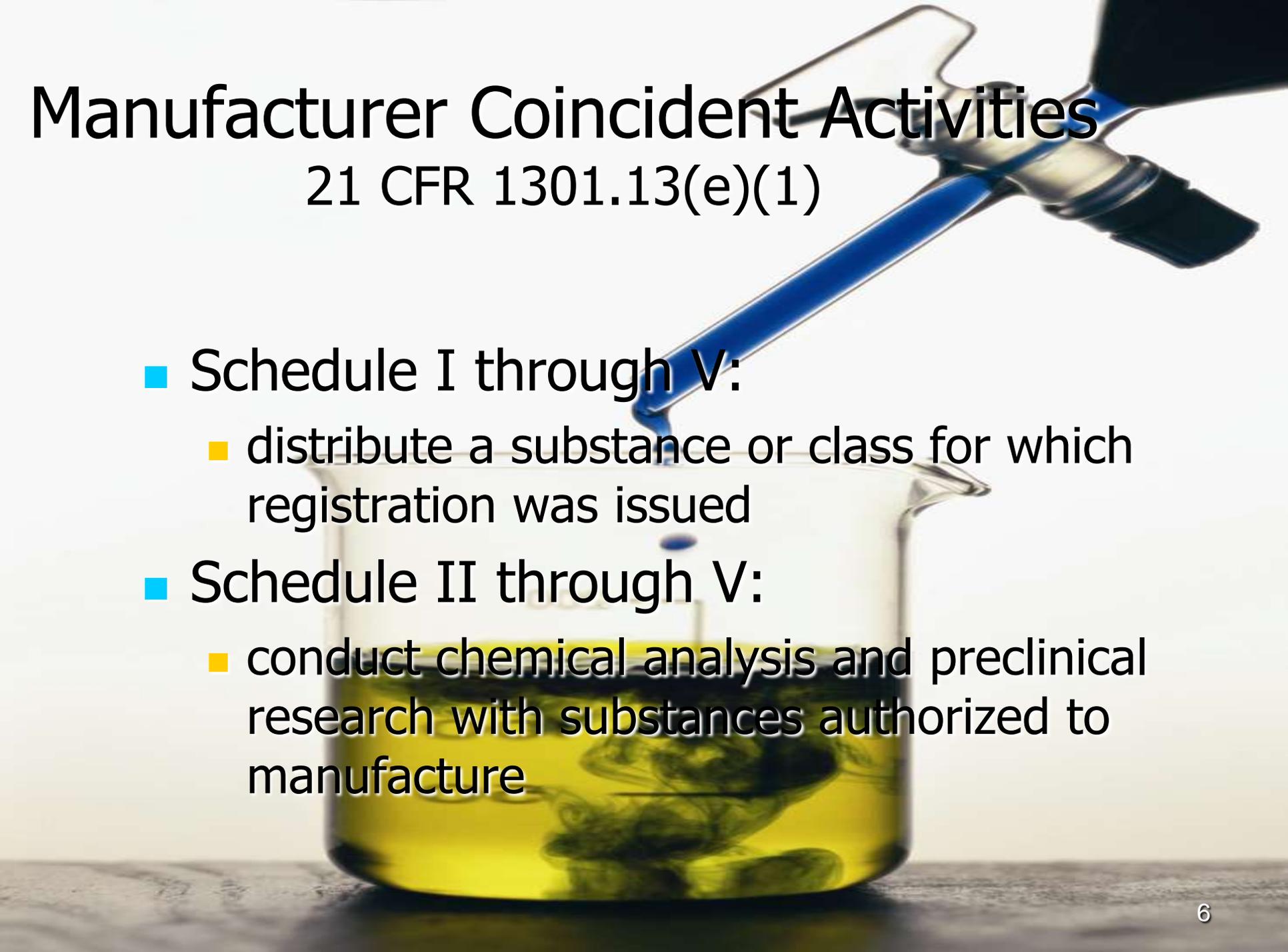
21 CFR 1301.13(e)(1)

- Schedules II through V:
 - chemical analysis
 - manufacture as set forth in statement
 - import substances for research purposes
 - distribute to persons registered to conduct research, chemical analysis, instructional activities

Research Activities

- Small amounts may be manufactured if the quantities are set forth in statement filed with the application for registration, **AND**
- The purpose as set forth in statement is to develop synthesis procedures or other research not related to dosage form development

Manufacturer Coincident Activities

A pipette is shown dispensing a blue liquid into a beaker. The beaker already contains a yellow liquid. The background is a light, neutral color.

21 CFR 1301.13(e)(1)

- Schedule I through V:
 - distribute a substance or class for which registration was issued
- Schedule II through V:
 - conduct chemical analysis and preclinical research with substances authorized to manufacture

Manufacturing Activities

- Purpose is to satisfy regulatory requirements such as FDA submissions or good manufacturing practice
- Establishing manufacturing processes and procedures (pilot, scale up, reformulation studies etc.)
- Development including bioavailability, formulation, stability and validation studies

Conclusion

- Once manufacturing moves beyond the scope of the research and becomes product development, those manufacturing activities are no longer considered to be coincident.
- Must meet requirements for registration as a manufacturer

Historical Determinations

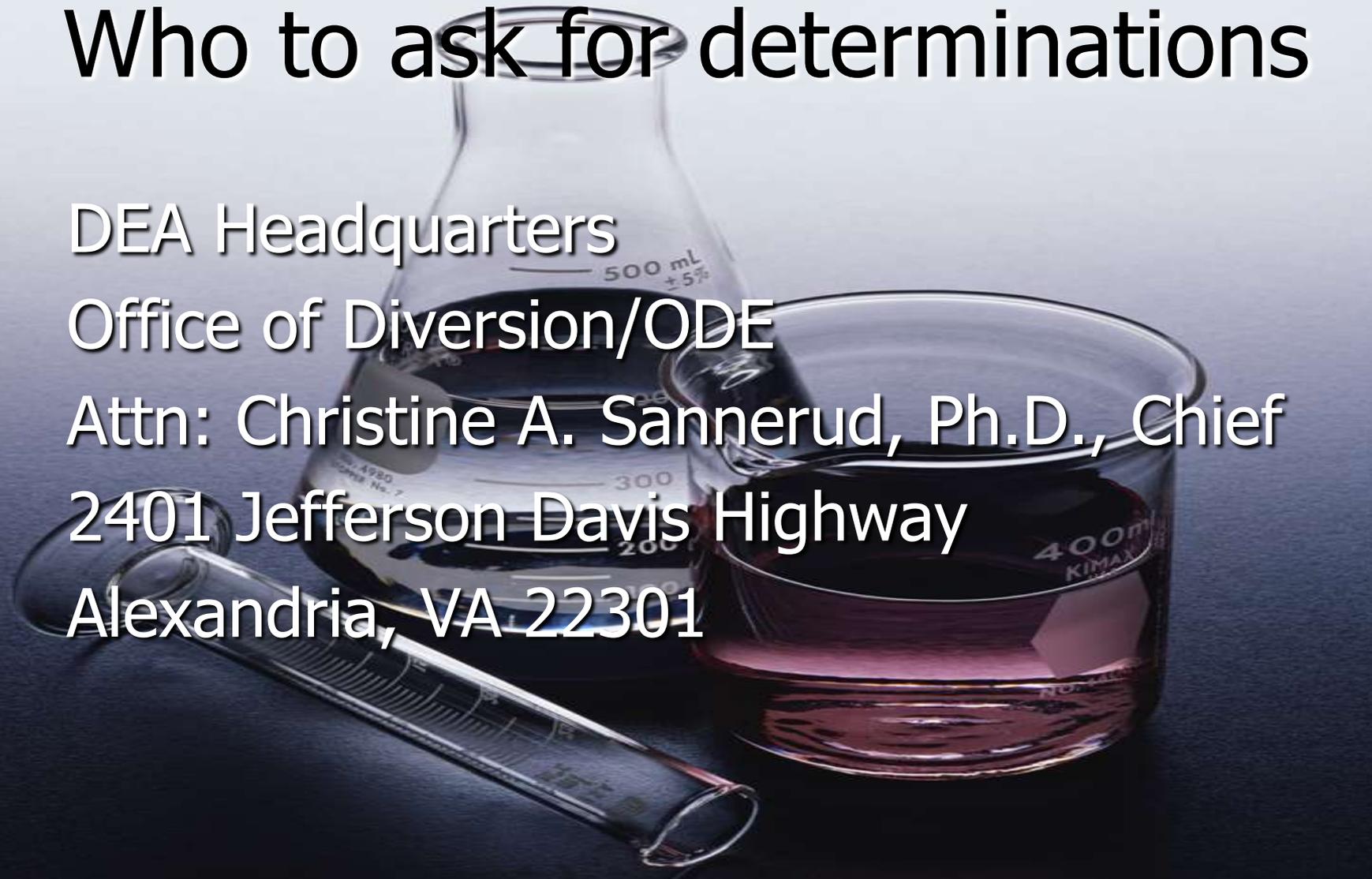
Manufacturing

- Validation
- Dosage forms for approval and testing, including clinical trials
- Stability
- Exhibit batches
- Rework processes
- Granulation development

Research

- Process parameters in laboratory
- Adhesive studies
- Laboratory testing
- Dosage release rate studies
- Conducting Clinical trials
- Synthesis route

Who to ask for determinations

The background of the slide features a photograph of laboratory glassware. In the center is a 500 mL Erlenmeyer flask containing a dark liquid. To its right is a 400 mL Kimax beaker, also containing a dark liquid. In the foreground, a graduated cylinder lies horizontally, partially overlapping the base of the flask and beaker. The glassware is set against a dark, reflective surface.

DEA Headquarters

Office of Diversion/ODE

Attn: Christine A. Sannerud, Ph.D., Chief

2401 Jefferson Davis Highway

Alexandria, VA 22301

Questions?

