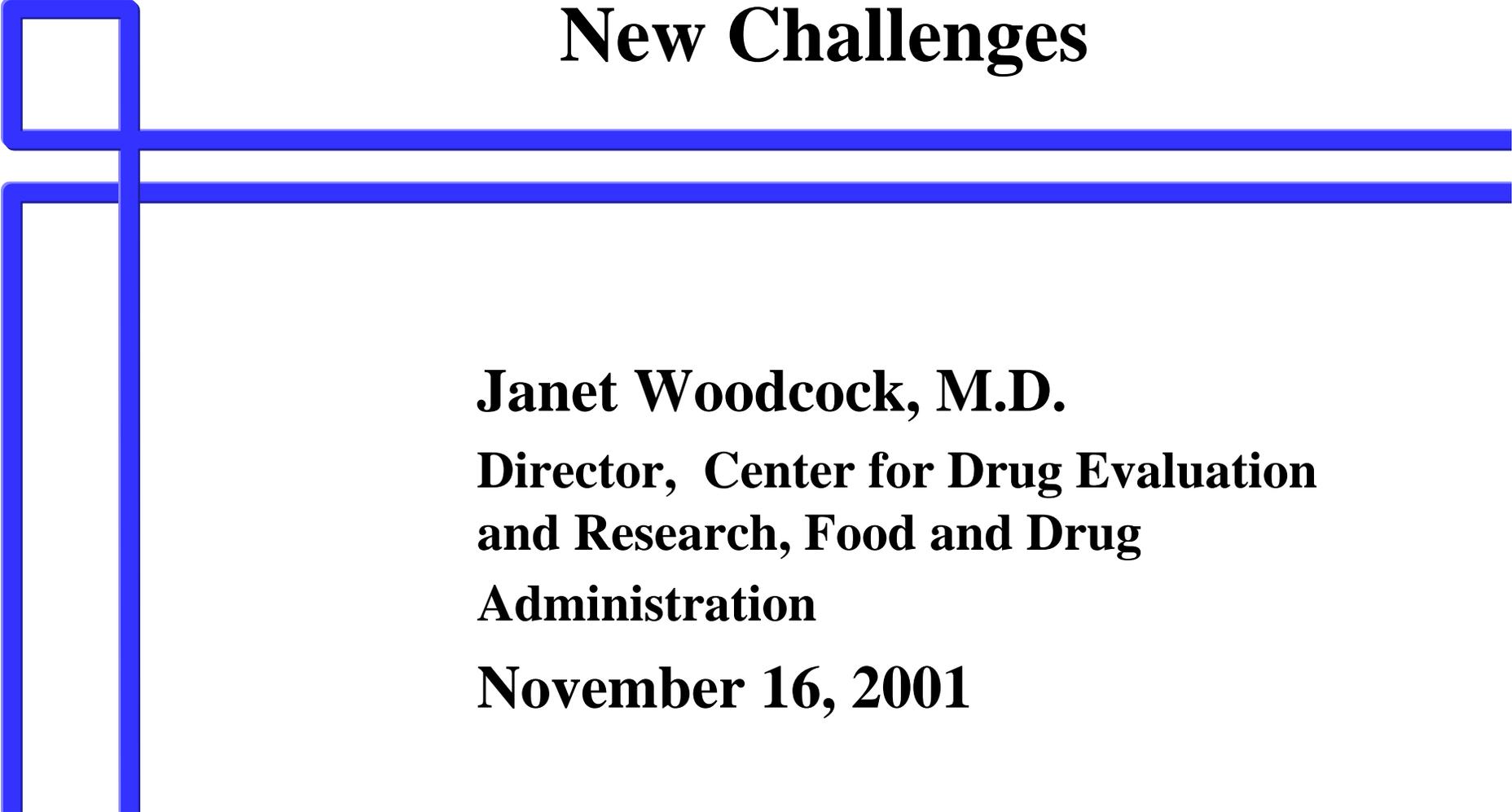


FDA Regulation of Drug Quality: New Challenges



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Regulation of Drug Quality: Current Status

- **Pharmaceutical industry manufacturing sector highly regulated**
- **FDA review and approval of process, documentation, and facility required prior to approval**
- **Many process changes require FDA review and approval prior to institution**
- **Ongoing manufacturing subject to FDA inspection and GMP standards conformance**

Current Status of System for Ensuring Drug Quality

- **US Drug products are of high quality, BUT**
- **Increasing trend toward manufacturing-related problems**
 - Recalls**
 - Disruption of manufacturing operations**
 - Loss of availability of essential drugs**
 - Negative impact on new drug approvals**

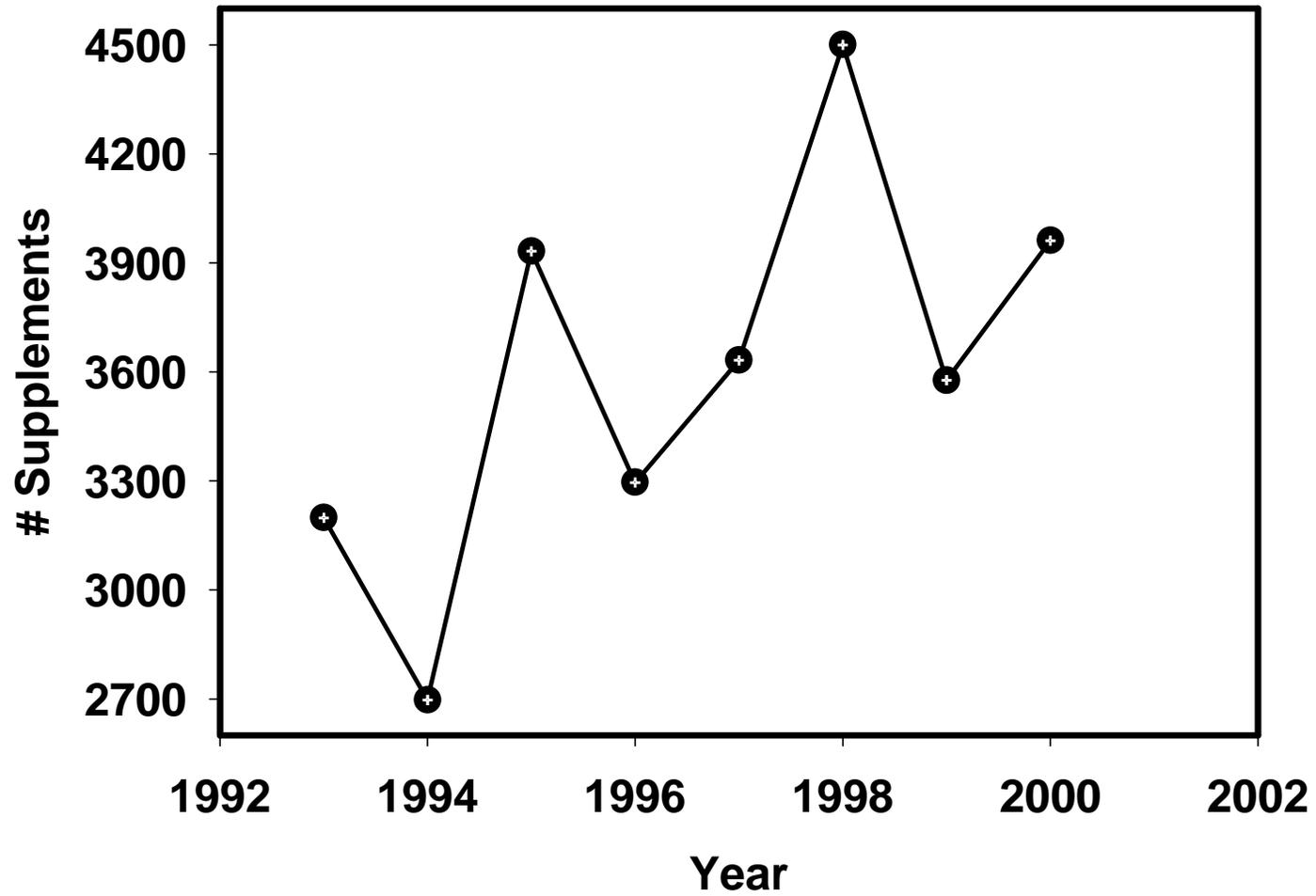
Current Status System for Ensuring Drug Quality, cont

- **US drug products are of high quality, BUT**
- **Low manufacturing and QA process efficiency-
-cost implications**
- **Innovation, modernization and adoption of new technologies slowed**
 - Introduction of new technologies in facilities not for US market**

Current Status System for Ensuring Drug Quality, cont

- **US Drug Products are of high quality, BUT**
- **High burden on FDA resources**
 - About 4,000 manufacturing supplements submitted yearly
 - FDA inspectors unable to meet statutory biennial GMP inspection requirement
 - Lower scrutiny of non-domestic industry

Post Approval Manufacturing Supplements



How Did We Get Here?

- **System evolved beginning 30-40 years ago--when sectors of industry lacked rigorous SOPs**
- **Science/technology base did not evolve as quickly as in other sectors**

How Did We Get Here? (CONT)

- **GMP standards are empirical, not science based**
- **International conference on Harmonization--consensus based standards (1990's)**
- **Industry--regulatory risk averse**

The Discovery-Development-Manufacturing Challenge

- **The drug discovery revolution**
 - identification of promising new molecular entities for development is not “rate-limiting”
- **Significant ongoing efforts to improve drug development processes**
 - minimize high attrition rates
- **Need for innovation in manufacturing process R&D**
 - significant, long-term, impact on public health and industry

Challenges for FDA

- **How to encourage innovation while ensuring high quality**
 - **Successful adoption of new technologies will IMPROVE overall quality**
- **How to successfully shift from empirical to science based standards for manufacturing process quality**

Challenges for FDA

- **How to decrease reliance on pre-approval review and physical evaluation**
- **How to recruit and train a scientific workforce proficient in application of new technologies**

Today's Approach

- **Presentation of Problem from variety of perspectives**
- **Use of PAT as an EXAMPLE of new technology**

Speakers

- **Doug Dean and Frances Bruttin (PricewaterhouseCoopers, Pharmaceutical Sector Team)**
- **G. K. Raju (Executive Director, MIT's Pharmaceutical Manufacturing Initiative)**
- **Norman Winskills (Vice President Global Manufacturing Services, Pfizer) and Steve Hammond (Manager, Process Analytical Support Group, Pfizer)**
- **Ajaz Hussain (FDA Deputy Director, Office of Pharmaceutical Science) - Regulatory perspective on new scientific approaches**

Questions for the Science Board

- **Are you able to support the approach?**
- **What resources do you suggest FDA draw on?**
- **Are there additional aspects to regulation of pharmaceutical quality that we should focus on?**