NIPTE is Supporting Translational Research in Academia

The Problem

- CTSA translational capabilities do not include management of clinical supplies.
- Most academic institutions are struggling with how to get clinical supplies that are vitally required for the success of the clinical trials in a cost-effective and timely manner.
- Managing Clinical Supplies is a critical component of Preclinical groups at successful pharmaceutical companies. This function normally consists of Chemical Development and Pharmaceutical Development groups which have significant people, pilot plant or contract development/manufacturing resources at their disposal. These resources enable these groups to meet the supply needs of the various clinical drug development teams.
- If the goal of the CTSIs' is to bring new and effective therapies for rare and neglected diseases and other patient unmet needs to the market then they need to partner with a strong complementary group who can help them to ensure that the clinical supplies will be available to them on-time and in a cost-effective manner (see attached figures of typical pharmaceutical company R&D organizations and R&D Clinical Project teams).
- The appropriate cost of managing clinical supplies needs to be budgeted into the CTSI awards. Making cGMP clinical supplies in the early stages of drug development can be very expensive and is a significant cost of bringing a new drug to the market. Cost of managing clinical supplies can be as much as 30 to 35% of the total cost of bringing a new drug to the market[1].

Managing Clinical Supplies

Sourcing clinical supplies on-time and cost-effectively requires a significant effort, expertise and expense. The mission of successful "Manage Clinical Supplies" organizations is to ensure that clinical supplies are never on the critical path for clinical trials. Some of the key objectives of these organizations are: which includes the following"

- Developing cost-effective manufacturing processes for the API and formulation in the laboratory.
- Sometimes, if the API is already available, sourcing it globally and assessing its quality.
- Developing analytical methods to identify and characterize the API and the raw materials, and to analyze and release the final drug. Sometimes, key in-process analytical methods also need to be developed to ensure successful manufacturing of these materials.
- Identification and auditing of suitable cost-effective cGMP manufacturers for often small quantities of these materials such as the API or the formulation.
- Transferring the manufacturing processes and analytical methods of the API and the formulation process to the manufacturers.

- Ensuring that all documents are in order and the suppliers have completed all documents in accordance to cGMP's.
- Getting the supplies made and released on time.
- Managing the entire supply chain to ensure quality, cost and timeliness of the clinical supplies.

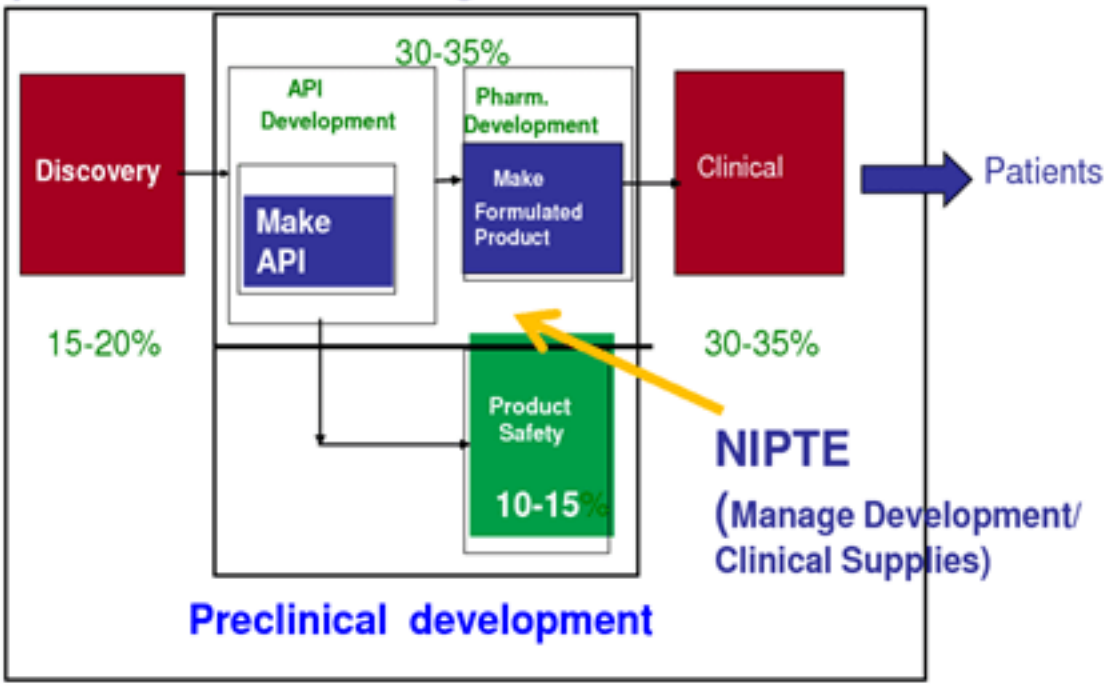
How NIPTE can help

- NIPTE's expertise includes global clinical supply sourcing, project management, regulatory management and support for Phases I and II
- cGMP manufacturing facilities in NIPTE's member institutions can support pre-clinical and clinical research by chemical synthesis and formulation of experimental new drugs
- NIPTE's faculty membership includes over two dozen leading academic experts in pharmaceutical science and engineering
- NIPTE has established connections with private companies and CRO that can provide support if necessary;
- NIPTE can become a **one stop shop** for clinical supplies for CTSA and provide services in API synthesis and drug manufacturing, regulatory support, CMC section support
- NIPTE aspires to become a national resource for the CTSA consortium and individual CTSI's around the country
- NIPTE Clinical Supplies Core Team includes:
    - Professor Stephen R. Byrn, University of Indiana, a world expert in pharmaceutical formulations;
    - Dr. Prabir K. Basu, NIPTE executive director and a former senior director for Global Manufacturing and Supply at Pfizer;
    - Dr. Vadim J. Gurvich, NIPTE associate director and director of API Process Development Core at the University of Minnesota.
- In addition, NIPTE capabilities include drug discovery, high-throughput screening, lead and probe discovery and medicinal chemistry.

Bibliography

1. Suresh, P., and Basu, P. K. " Improving Pharmaceutical Product Development and Manufacturing: Impact on Cost of Drug Development and Cost of Goods Sold of Pharmaceuticals" , J. Pharmaceutical Innovation, Volume 3, 175-187, September 2008

Typical role of a Manage Development Supply organization In a pharmaceutical R&D organization



Process: Manage Development Supplies
Materials: Clinical Supplies

Typical Clinical Project Teams at Pharmaceutical R&D Organizations and Role of NIPTE