K-State Olathe Animal Health Regulatory Affairs
CRO – Sponsor Relationships
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Historically

▶ The pharmaceutical industry had many companies with relatively narrow product lines.

▶ Animal health companies (pharmaceutical) were owned by larger, human health companies. Animal health vaccine companies tended to develop independently, some of which were acquired by large companies later.

▶ Most companies were vertically integrated to include discovery, development, regulatory approval, marketing and sales.

Outsourcing as a business model

- For most of the 20th century, business models focused on own, manage and directly control. This was the model that the US pharmaceutical industry followed as well.

- Diversification efforts of the 60s were engaged to take advantage of economics of scale and companies started acquire other companies to protect profit, however, multiple layers of management ensued.

- Outsourcing was not formally identified as a strategy until 1989 (Mullin)

Outsourcing gains traction

- By the 1990s many organizations were starting to outsource the universally common functions of business.
  - Printing
  - Data processing
  - Internal main distribution
  - Food services
  - Security
  - Other types of good housekeeping tasks

Outsourcing with strategic partners as part of a strategic plan

- The model was applied to much more complex and specialized needs
- Core business function were included
  - Discovery
  - Development
  - Regulatory Approval
  - Technical Support
  - Customer Service

Why do companies outsource

- Lower operational costs
- Maintain or reduce company headcount in times of expansion
- Manage risk associated with outsourced activities
- Gain access to world-class capabilities and expertise
- Third party relationship clout
- Free internal resources for other purposes
- Share risk with a strategic partner

Outsourcing – a contemporary definition

The strategic use of outside resources to perform activities traditionally performed internally by company employees.

Critical Factors for Success

- Understand company goals and objectives

- A shared vision

- Select the right vendor or client

- Continuous assessment and improvement in management relations

- Contractual agreements that appropriately distribute risk and responsibility

- Senior management support

- A carefully developed and religiously implemented communication plan

- Clear understanding of chain of command from both organizations

Ten Thousand Hours – the MVS Analogy

▶ Malcom Gladwell's 2008 book, *Outliers describes the 10,000 hour rule (Bill Gates programming & early gigs by The Beatles before invading America)*

▶ *Our business started as mixed animal practice in 1987 with an area of expertise in microbiology*

▶ *Corporate clients all had their own farms, but needed help with overflow*

▶ *The basis was the personal relationships with friends that I met along the way*

▶ *By 1991, I'd estimate that I had my 10,000 hours "in"*

▶ *By the year 2000, we realized that their was a real "need"*

▶ *By 2004, the acronym, CRO was being commonly used to refer to our type of organization*

Our Business

▶ Helping our customers evaluate

  ▶ Safety and Efficacy of products for FDA/USDA/EPA approval

  ▶ Determine appropriate models to provide clinically relevant data

  ▶ Test model concepts in clinical (field) trials including multi-site studies

CRO Assessment

- ▶ Price
- ▶ Quality
- ▶ Speed

Critical Components for Research

▶ Knowledge and Commitment to meeting the needs of the animals and staff

▶ Knowledge of Commitment to understanding the advantages and limitation of models

▶ Knowledge and Commitment to Quality

▶ Knowledge and Commitment to Compliance

▶ Follow Through

We deal with a high degree of diversity in our project mix – however – projects all have these needs in common

▶ Study Design to match regulatory need and applicable to use

▶ Data Capture to fulfill the intentions of the protocol

▶ Conduct the work in a fashion compliant to regulations

▶ Conduct the work in a fashion applicable to field use

▶ Conduct the work in a fashion that is repeatable

"What can possibly go wrong?"
A few things to be aware of..

▶ Data Capture Systems should be designed to "Capture Data", not necessarily for the convenience of QC, QA or folks watching

▶ Electronic Data Capture as well as conventional methods

▶ Procurement has a place, but cutting off one leg of the stool does not serve the long term needs of the industry (lowest cost is not necessarily the highest value)

▶ Medical research is not a "commodity"

▶ Communication and IP, secure files

"What can possibly go wrong?"
A few things to be aware of..

- Intellectual Property in today's world
  - Turn over of Key Personnel
  - Hackers
  - Secure Files and accidental file transfer
  - International use of IP
- Date Issues
  - What do you need and how will you analyze?
  - Quality or not at all
  - Ensure acceptance of the plan before you start

"What can possibly go wrong?"
A few things to be aware of..

▶ Legal Issues can/have emerged parallel to the use of CRO

    ▶ Contracts can attempt to limit financial obligation of sponsor in a research environment that is difficult if not impossible to control

    ▶ When corporate clients show up to meetings with attorneys instead of scientists, the relationship changes

    ▶ Ask the question, how did companies handle unfavorable results when they owned all of their own farms?

    ▶ Strive to "over communicate" when protocol application problems are noted

    ▶ Make sure that both parties have identified the responsible party

Summary
We are all in this together!

- ▶ Corporate Sponsors (with responsibility to shareholders)

- ▶ CROs (with responsibility to animals and staff in our care)

- ▶ Regulators (with responsibility to consumers)

- ▶ Academicians/educators (with responsibility to educate and mentor – to provide professionals for all of the above sectors)

- ▶ Quality/Compliance Professionals (with responsibility to components of all of the above)

- ▶ We all need to strive to help each other understand the needs and responsibilities

Thank you K-State Olathe for making this interaction possible

▶ Dr. Ralph Richardson

▶ Dr. Paul Cassidy

▶ Angelica Buzard

▶ All Meeting Participants