

Company Profile

Industry Sector: Analytic services supporting quality control of pharmaceutical biotechnology products

Company Overview: Precision Bioassay provides statistical solutions to practical problems in biological assays. These assays are used in lot release and stability studies of pharmaceutical protein, vaccine, cell therapy, and gene therapy products. We provide customized collections of standardized modules to organizations that require high performance from biological assays. These modules include designs, analysis methods implemented in software, sophisticated use of robotics, concise reporting, validation designs, validation analyses, as well as consulting support to both accelerate assay development and validation as well as facilitate approval from regulatory agencies.

Target Market(s): Pharmaceutical and biotechnology companies bringing protein, vaccine, gene therapy, or cell therapy products to market.

Key Value Drivers

Technology: Our collection of standardized modules includes:

- Designs for linear and nonlinear models,
- Outlier detection methods that exploit the special structure of bioassay designs,
- Mixed model analysis methods for both types of designs,
- Comprehensive yet concise reporting of bioassay results,
- Software to drive pipetting robots to perform good designs with randomization,
- Validation designs, coupled with validation analysis methods, and
- Design of experiment methods adapted to common laboratory issues in bioassay.

Competitive Advantage: By combining good design and appropriate modern analysis we improve the precision of bioassays substantially. This can reduce the cost of running a bioassay by \$500,000/year for a biotechnology product. More importantly, we accelerate the bioassay development and validation process.

Plan & Strategy: Move to market quickly with limited capabilities, new features in pipe.

*Technology funded by NIH (NCRR) and moving towards commercialization with NIH-CAP support

Management

Leadership:

Dr. David Lansky, Owner and President
BS Botany, MS Entomology, MS & PhD Biometry
Business management experience 8+ years
Pharmaceutical industry experience 16+ years

Dr. Carrie Wager, Principal Statistician
BS Biometry, PhD Biostatistics
Statistical programming 10+ years
Statistical consulting experience 5+ years

Product Pipeline

Xymp: Web-based bioassay software containing a collection of designs, provides files to drive lab robots to perform randomized bioassays, performs bioassay analysis.

- Currently a working prototype
- Alpha version expected Q2 2008
- Beta version expected Q4 2008
- Production version expected Q2 2009

Additional capabilities for future versions:

- Design of experiments tools for robotic bioassay
- Validation tools (designs and analysis) for robotic bioassay
- Neutralizing antibody bioassays, designs and analyses with improved sensitivity
- Drug combination designs and analysis methods for bioassays

