

Diane V. Doughty

PROPOSAL ABSTRACT (2007)

Rational Selection of Programming Settings for Automated Actuation of Nasal Sprays and Metered Dose Inhalers based on Hand Profiles

The FDA recommends using automatic actuation systems for *in vitro* tests in place of potentially variable hand-firing, and that the settings should be relevant to patient use. However, the selection of settings for these systems is poorly understood and documented. Therefore, these studies will derive justifiable and relevant settings for automated actuation systems using an over-the-counter nasal spray pump with adult participants, two commercial pressurized metered dose inhalers (pMDIs) in adults, and a prescription nasal spray pump with adults and children as participants. The effect of the participant-related variability on the product performance will be measured with studies of shot weight and droplet size determination. Participants will be asked to hold the unit in a hand actuation monitor that records force and displacement data in 5ms intervals. This data will be translated into displacement versus time and force versus time profiles from which settings can be extracted for force-controlled and velocity-controlled actuation systems. Mean settings and settings 2SD from the mean, which represents the variability seen in hand-firing, will be programmed into the systems. Shot weights and droplet size will be measured to determine if the variability has a significant effect on the performance of the nasal spray pump or pMDI. Differences between adult and pediatric extracted actuator settings will be noted, as will general differences between the actuation of pMDI products. Handedness will be recorded to determine if the extracted settings differ significantly from actuations performed with the dominant versus non-dominant hand.

EDUCATION

Ph.D. in Pharmaceutical Sciences

University of Maryland, Baltimore
Advisor: Richard N. Dalby, Ph.D.

2005 - Present

B.S. in Biology with a concentration in genetics

The Pennsylvania State University at University Park

2001 - 2004

RESEARCH EXPERIENCE

RESEARCH PROJECT, AEROSOL LABORATORY

University of Maryland, Baltimore

Advisor: Richard N. Dalby, Ph.D.

Summer 2006 - Present

- Conduct volunteer studies with adult and pediatric participants to generate displacement vs. time and force vs. time profiles using Hand Actuation Monitors (HAM) to determine patient-relevant settings for velocity-controlled and force-controlled automatic actuation systems for nasal spray pumps and metered dose inhalers
- Utilize actuator parameters on velocity-controlled and force-controlled robotic systems to determine if the patient-derived variability is associated with significant differences in pump performance.

ROTATION PROJECT, AEROSOL LABORATORY

Spring 2006 – Summer 2007

University of Maryland, Baltimore

Mentor: Richard N. Dalby, Ph.D.

- Developed a modified nasal spray pump consisting of a weighted, flexible dip tube to replace the traditional rigid dip tube
- Compared the ability of the flexible and rigid dip tubes to diminish the amount of formulation wasted and improve the content uniformity as the bottle empties in five nasal spray pump products

LABORATORY ROTATION PROJECT

Fall 2005

University of Maryland, Baltimore

Mentor: Hamid Ghandehari, Ph.D.

- Optimized procedures for the extraction and purification of adenoviral DNA for targeted gene delivery after polymeric release
- Utilized RT-PCR to amplify adenoviral DNA and determine its concentration by comparison to standards

EMPLOYMENT SUMMARY

PHARMACEUTICS LABORATORY TEACHING ASSISTANT

Spring 2006

University of Maryland, Baltimore

Instructor: Stephen Hoag, Ph.D.

- Responsible for lab preparation, upkeep during session and breakdown
- Knowledgeable in lab topics to field questions by over 40 Pharm.D. students
- Conducted particle sizing and tableting demonstrations
- Proctored and graded exams

TEACHING ASSISTANT, COMPOUNDING LABORATORY

Fall 2005

University of Maryland, Baltimore

Instructors: Richard N. Dalby, Ph.D. & James Polli, Ph.D.

- Assisted in lab setup, maintenance and cleanup and answered questions posed by Pharm.D. students
- Proctored exam and gave a presentation of a pre-lab to Pharm.D. students

QUALITY CONTROL LABORATORY INTERNSHIP

Spring & Summer 2005

Teva Pharmaceuticals USA, Sellersville, PA

Mentor: Anthony D'Ippolito

- Interned as an analyst for both sample and standard preparation for stability and/or release quality control testing for tablets, capsules and semi-solid pharmaceutical products
- Conducted tests such as identification by Infrared Spectrophotometry or TLC, assays, dissolution testing, dissolution profile testing, water content determination, content uniformity, blend uniformity, particle sizing and disintegration testing
- Trained on the documentation of test results for both paper and paperless systems

STABILITY SERVICES INTERNSHIP

Summer 2004

Teva Pharmaceuticals USA, Sellersville, PA

Mentor: Linda Gerhart

- Log and maintain pharmaceutical stability samples for PR&D and finished products
- Record, audit and file stability sample paperwork as it arrived from the QC and PR&D Laboratories.
- Convert stability sample records from paper to the paperless LIMS system

PHARMACEUTICAL RESEARCH AND DEVELOPMENT INTERNSHIP
Teva Pharmaceuticals USA, Sellersville, PA

Summer 2002 & 2003

Mentor: Robert Gwozdz

- Assisted in the development and manufacturing of novel drug delivery formulations in a technology applications group for tablets, capsules and oral suspensions on both the pilot lab and GMP manufacturing scale
- Trained on the use of a variety of manufacturing processes such as blending, granulation, tableting and coating
- Responsible for upkeep of compliant laboratory notebook for the documentation of all batches.

PUBLICATIONS

Doughty DV and RN Dalby (2007). Determination of automated nasal actuator parameters based on a twenty volunteer study. *Respiratory Drug Delivery Europe 2007*, 349-352.

POSTER ABSTRACTS

Doughty DV and RN Dalby. Handedness and Gender Effects on the Derivation of Machine Actuation Parameters for Nasal Sprays. Abstract No. W5252. American Association of Pharmaceutical Scientists Annual Meeting 2007, San Diego, CA.

Hsu W, **DV Doughty** and RN Dalby. The effect of volunteer study-derived actuation parameters on sprayed droplet size. Abstract No. W5253. American Association of Pharmaceutical Scientists Annual Meeting 2007, San Diego, CA.

Diao L, **DV Doughty** and RN Dalby. Influence of shaking on the spray weight of nasal spray pumps. Abstract No. W. American Association of Pharmaceutical Scientists Annual Meeting 2007, San Diego, CA.

Doughty DV and RN Dalby. Modification of nasal spray dip tubes to decrease formulation waste and improve content uniformity by decreasing the number of sprays in the tail-off period. Parenteral Drug Association Annual Meeting 2007, Las Vegas, NV.

Doughty DV and RN Dalby. An investigation of modified nasal spray dip tubes to determine the influence on bottle emptying. Philadelphia Pharmaceutical Forum Poster Night 2007, Ambler, PA.

Doughty DV and RN Dalby. A Novel Way to Increase the Efficiency of Nasal Spray Pumps. Abstract No. M1262. American Association of Pharmaceutical Scientists Annual Meeting 2006, San Antonio, TX.

PRESENTATIONS

- "Ointments and Semi-Solids", PHAR 535 Pharmaceutics Pre-Lab (2008)
- "Introduction to Pharmaceutical Aerosols", PHAR 535 Pharmaceutics (2008)
- "Gels and More Challenging Ointments", PHMY 591 Compounding Pre-Lab (2007)
- Inhalation Devices Demonstration (2007)
- "Extraction of Automated Actuator Parameters from Hand Data", Respiratory Drug Delivery Europe 2007 Workshop with InnoVaSystems, Inc.
- "Genetically Engineered SELP-47K for Local Adenovirus Delivery to Head and Neck Cancers", Summary of rotation studies presented to the Ghandehari Laboratory (2006).
- "More Challenging Topical Products", PHMY 591 Compounding Pre-Lab (2005).

AWARDS & HONORS

- 2007-2008 University of Maryland, Baltimore Department of Pharmaceutical Sciences Teaching Award (\$2,000)
- 2007-2008 Josiah Kirby Lilly, Sr. Memorial – AFPE Pre-Doctoral Fellowship in the Pharmaceutical Sciences (\$11,000)
- 2007 AFPE Pharmaceutical Sciences Graduate Student Recognition Award (\$1,500)
- 2006 AAPS Student Chapter sponsored Travel Award (\$200)
- 2004 Service award for Theta Kappa Pi (Penn State local service sorority)
- AP Scholar with Distinction

ORGANIZATIONS

American Association of Pharmaceutical Scientists (AAPS), member since 2005

AAPS UMB Student Chapter: Chair (2007-2008), Vice-Chair (2006-2007), Treasurer (2005-2006), Webmaster (2005-2008).

Pharmacy Graduate Student Association (PGSA), University of Maryland, Baltimore
Member since 2005, President (2006-2007)

The Rho Chi Pharmacy Honor Society, Omicron Chapter, inducted Spring 2007.

SKILLS & QUALIFICATIONS

RESEARCH

Diosna, Fluid Bed (Top Spray, Bottom Spray, Drying), Moisture Analyzer, Comil, Fitz Mill, V-Blender, Tablet Press (Betapress, Rotary press), Tablet Pan Coater, Dissolution Baths, Sonic Sieve Shaker, UV Spectrophotometer, Karl Fischer Titration, Real Time-PCR (iCycler), Western Blot, Gel Electrophoresis, Metal Ion Affinity Column, Mastersizer S (Malvern), Spaytec (Malvern), Pump Actuation and Weight Station (PAWS, InnovaSystems, Inc.), Velocity Actuator (VA, InnovaSystems, Inc.), Hand Actuation Monitor (HAM, InnovaSystems, Inc.)

COMPUTER

Microsoft Windows, Microsoft Office, Lotus Notes, HTML, Laboratory Information Management System (LIMS), InnovaSystems, Inc. automated actuator software