

SR. SCIENTIST

Career Focus

To seek for a position in pharmaceutical industry, particularly in the areas of pharmaceutical product developments through innovation in formulation, application of novel excipients and optimization of current processes.

Highlight of strengths Advanced knowledge and experiences in controlled drug delivery technologies including oral immediate, time-delayed, sustained releases and site-specific delivery systems, sustained sub-Q injectable and long-lasting topical systems. Extensive experiences (over 10 years) in pharmaceutical dosage form developments including injectable, oral soft gel capsules, topical dosage form for small molecular drugs, nutrients and bio-macromolecules. Active in tracking and identifying new technology opportunities and developing innovative solutions; Green Belt certified with extensive experiences in applying Lean Sigma principles and tools (DOE and statistics) to developmental activities to identify critical factors to the product quality (Quality by Design) or root causes to the problem. Prior supervision and leadership experiences.

Core Qualifications

Quality by design Project management Experiment design Polymer synthesis Polymerizations Polymer analysis Polymer tests Rheology/texture analysis Analytical chemistry Coating/granulation Batch record paperwork Scale-up/pilot/production GC/LC/MS GLP/GMP Six Sigma/Lean

Education

Ph.D : Polymer Science , 1995 Wuhan University ¼ City , China Polymer Science

M.S : Polymer Science , 1988 Wuhan University ¼ City , China Polymer Science

B.S : Polymer Science , 1982 Wuhan University ¼ City , China Polymer Science

Skills

acid, active pharmaceutical ingredients, approach, cancer, crystal, delivery, design of experiment, DNA, experiments, forms, GC, GMP, HPLC, innovation, IP, materials, exchange, Natural, novel, Optimization, packaging, product development, project leader, project management, Six Sigma, Type

Experience

Sr. Scientist

December 2009 to Current Bristol Myers Squibb ¼ Orlando , FL

- Softgel capsule formulation development for a number of active pharmaceutical ingredients and nutritional supplements in the forms of softgel capsule, chewable and lozenge, from concepts to clinic and commercial production.
- Optimization of enteric gel mass and innovation of new pectin-based Type-A gelatin enteric gel mass (All Natural Ingredients).
- Accomplishment includes patent application and two process change recommendations.
- Development of innovative site targeting drug delivery (to the colon) softgel platform, achievement includes IP disclosure.
- Extended release, abuse deterrent and anti over ingestion softgel fill formulation developments.
- Developing solutions to encapsulate water sensitive drugs (such as aspirin) into softgel capsules, Supports to the development of carrageenan/starch based non-animal gel mass achieving working gel mass formulation and encapsulation process.
- New technology exploration and assessments including drug ion liquids, new material potentially applicable to company's new product developments and existing product improvements.
- Development of test methods including rheology, texture analysis, dissolution and HPLC methods for softgel products and ingredients characterizations.
- Formulation project management including GMP batch record writing and review, raw material qualification, batch preparation for clinic study, finish product assay and stability study.
- Passed Six Sigma training program including design of experiment and a Green Belt certified.

Scientist

November 2003 to December 2009 Abcam Plc ¼ Milpitas , CA

- Drug delivery technology and product developments: Injectable sustained release delivery technology based on drug-fatty acid salt, drug-amino acid ester salt, drug-lipid complex; Injectable anti-biotics formulation for long lasting action.
- Accomplishment included FDA submission.
- Lipid gel drug delivery technology and topical multi-active formulation effective treatment to chronic ear infections; Accomplishment included technology transfer to major pharma company.
- Protein-, siRNA-lipid complex injectable hydrogel delivery system.
- Accomplishment includes IP, achieving high concentration and sustained release that exceeded customer's requirements.
- Analytical method developments for new drug product development, including GC, HPLC, LC-MS, release rate test, raw material and finished product physiochemical characterizations, stability and degradants quantification.
- Bio-analytical method developments and applications in protein (fatty acid binding proteins) isolation, purification and structural identification, by means of size, ion exchange, affinity chromatography and HPLC-MS.
- Process developments: Developing scale-up process; preparing formulations under GMP for clinic studies, evaluating and selecting packaging materials.
- As a project leader developed project strategies and plans/timelines, supervised a group of associates' work, searched literature, designed and hand-on performed experiments, summarized and reviewed data, and reported results.

Research Scientist

August 2000 to October 2003 Grifols Inc. ¼ Newport News , VA

- Established a gene delivery system based on calcium phosphate/DNA nano-particles for bone tissue engineering, work published.
- Established project on new injectable starch-based biodegradable hydrogels for cell delivery in tissue engineering, fund granted from National Institute of Health.
- Established novel approach to construct three-dimensional porous polymer scaffolds as implants to delivery cells and growth factors in bone tissue engineering, work published.

- Evaluated biocompatible and biodegradable polymers, such as PLA/PLGA, fibrin, hyaluronic acid, for controlled drug release and bone tissue engineering.
- Fibrin was selected as main component in building tissue engineering implants in situ by inkjet printing, part of the work published.

Postdoctoral Associate

July 1998 to July 2000 International Association For Great Lakes Research 1/4 Superior , WI

- Established biodegradable polymeric macroporous matrices as implants for delivery of growth factors and for cells in bone tissue regeneration, work published.
- Fabricated porous polysaccharide sponges for cartilage regeneration.
- Evaluated interaction of polymer material with cells and tissues.
- Cell growth was significantly improved through grafting RGD peptide on hydrophobic PLGA porous scaffold surface, work published.
- Established methodology to prepare microspheres (microencapsulation) for controlled drug release in brain cancer treatment, work published.

Post-doctoral Associate

May 1997 to July 1998 University Of Massachusetts Medical School 1/4 Brockton , MA

- Developed a new approach to fabricate biodegradable polymeric macroporous scaffolds as implants for bone tissue regeneration, work published.
- Synthesized and evaluated surface property of fluorinated polymer materials, work published.
- Synthesized and evaluated physicochemical properties of self-assembly fluorinated liquid crystal grafted polysiloxanes mono-layers.
- Synthesized and evaluated polysiloxanes grafted with poly(ethylene glycol) containing activated ester group which possesses specific protein and DNA segment adsorption properties, work published.
- Investigated ultra-high molecular weight polyethylene for artificial joints replacement, and surface modification to improve its lubrication, work published.

Publications

Conference presentations Y. Hu, Q. Fang, A. Fatmi, Fill Compositions for Extended Release Softgel Capsules, Poster presentation at 2013 AAPS in San Antonio, Nov 2013. N. Yu, Y. Hu, Q. Fang, Extended release of IBU from Hot-melt extrusion matrices, Poster presentation at 2012 AAPS in Chicago, Nov 2012. Y. Hu, Q. Fang, M. Hariharan, Incorporating polymers in softgel capsules for extended release, poster presentation at the 39th Controlled Release Society Conference, July 2012, Quebec, Canada. Y. Hu, Q. Fang, N. Yu, S. Majuru, M. Hariharan, Development and Characterization of a Capsule Dosage Form for Colon Targeting Drug Delivery, poster presentation to 2010 AAPS in New Orleans in Nov. 2010. Y. Hu, Q. Fang, N. Yu, S. Majuru, M. Hariharan, Developing enteric gel mass for softgel encapsulation, poster presentation to 2010 AAPS in New Orleans in Nov. 2010. S. Carter, Y. Hu, J. Heflin, Q. Fang, N. Yu, S. Majuru, M. Hariharan, Gel permeation chromatography (GPC) characterizations of gelatin used in softgel encapsulation, poster presentation to 2010 AAPS in New Orleans in Nov. 2010. Y. Hu, Q. Fang, N. Yu, S. Majuru, Developing softgel dosage form for colonic drug delivery, poster presentation at Controlled Release Society Conference, July 2010, Portland, OR. PUBLICATIONS (30+, complete list available upon request) Y. Hu, H. Fu and J. O. Hollinger, A novel calcium phosphate-based gene delivery system for bone tissue engineering, *J Biomed Mater Res*, 2005, 74A, 40-48. Y. Hu, S.R. Winn, Ian Krajchich and J.O. Hollinger, Porous polymer scaffolds surface modified with arginine-glycine-aspartic acid enhance bone cell attachment and differentiation In Vitro, *J Biomed Mater Res*, 2003, 64A, 583-590. Y. Hu, D.W. Grainger, S.W. Winn and J.O. Hollinger, Fabrication of poly(-hydroxy acid) foam structures with multiple solvent systems, *J Biomed Mater Res*, 2002, 59(3), 563-572. N. Xia, Y. Hu, D.W. Grainger and D.G. Castner, Functionalized poly(ethylene glycol)-grafted polysiloxane monolayers for control of protein binding, *Langmuir*, 2002, 18, 3255-3262. T.M. Meese, Y. Hu, R.W. Nowak and K.G. Marra. Surface studies of coated polymer microspheres and protein release from tissue-engineered scaffolds, *J Biomater Sci, Polym Ed*, 2002,13, 141-151. Y. Hu, J.O. Hollinger, and K.G. Marra, Controlled release from coated microparticles embedded in tissue-engineered scaffolds. *J Drug Targeting*, 2001, 9, 431-438. G.P. Beauregard, Y. Hu, D.W. Grainger and S.P. James, Silylation of poly-L-lysine hydrobromide improves dissolution in apolar organic solvents, *J Appl Polym Sci*, 2001,79(12), 2264-2271. K.G. Marra, P.G. Campbell, Y. Hu and J.O. Hollinger, "Fundamental physiological factors directing bone tissue engineering design and development", in "Tissue Engineering and Biodegradable Equivalents", Editors: Lewandrowski, Trantolo, Gresser, Yaszemski and Altobelli, 2001, p25-43. D.F. Emerich, S.R. Winn, Y. Hu, J. Marsh, P. Snodgrass, D. La Freniere, T. Wiens, B.P. Hassler and R.T. Bartus, Injectable chemotherapeutic microspheres and glioma I: Enhanced survival following implantation into the cavity wall of debulked tumors, *Pharm Res*, 2000, 17(7), 767-775. S.R. Winn, Y. Hu, C. Sfeir and J.O. Hollinger, Gene therapy approaches for modulating bone regeneration, *Adv Drug Del Rev*, 2000, 42, 121. 3 2 6 6