Scientific Affairs Committee (SAC)

Research Cycle Process

Current and Previous Projects

Annual Business Meeting

As of May 28, 2010

Scientific Affairs Committee (SAC)

“Propelling Industry-Academia Relations Through Collaborations and Scientific Mindshare”

AGENDA

I. Welcoming Remarks & Introduction

A. Meeting Objectives and Overview of SAC
B. Progress or Status Presentations of Current Projects under Funding (3)
C. Presentations by PI's of the Proposals (3) Submitted for Funding Considerations [Renewals (3) / New (1)]
D. Review of Procedures - Evaluation and Selection of Projects for Funding

II. Lunch

III. Other Agenda Items:

A. Considerations for Research Cycle Options and Timetable Definition for the fiscal year 2009/2010
B. Generation of Topics for the Research Cycle of Fiscal Year 2010/2011
C. Initiatives under Development by the Life Science Alliance that will Impact INDUNIV-SAC
D. Other Areas for Future Development and Alternatives for Enhancing Pool of Research Funds
E. Upcoming Conferences sponsored or endorsed by INDUNIV

Scientific Affairs Committee (SAC)
Charter

"Propelling Industry-Academia Relations Through Collaborations and Scientific Mindshare"

- **Vision:**

  Catalyze research and development of science and technology in Puerto Rico.

- **Mission:**

  To recommend the awarding of grants to challenging and industry relevant research project proposals while synergizing additional scientific interactions.

Scientific Affairs Committee (SAC)

Definition

- Working group composed of scientists and managers from both industry and academia which defines the specific areas of interest for our annual requests for proposals and evaluates the proposals, making recommendations to the Board for their approval. Once approved facilitates their monitoring towards their completion.

- Given our growth, broader INDUNIV's constituency and sphere of activity goes beyond the traditional field of pharmaceuticals, this participation by your representatives in the SAC Team could significantly impact our future grantmaking policy. As a member of the SAC you will help define the subject areas in which grants will be awarded plus augment the value added of the team in terms of an ample spectrum of contributions

Scientific Affairs Committee (SAC)

- **Manages the Research Cycle and Call for Proposals Process**
- **Oversees the Progress of the Projects, Participates in Advisory Initiatives**
- **Has awarded >2.7 M in Grants in ~ 57 projects since its foundation in 1985**
- **2008 – 2009 is also sponsoring three projects of 100 K and anticpates a similar scenario for the 2009-2010 funding to be awarded today**

Advisors

- **Dr. Ana Cocero(Abbott-PP) / M.Medina**
- **Drs. Grisell Gómez/J.Ponzo (Abbott-BP)**
- **Ms. Amaryllis Alsina (Abbott DP)**
- **Dr. Zulma Santiago (Amgen)**
- **Alternate pending (Amgen)**
- **Dr. C. Conde (Pfizer-G) / Dr. José Perez**
- **Dr. José Cruz Torres (Pfizer)**
- **Enriqueta Serrano (Pfizer)**
- **Pending Confrmation: CPM**
- **Pending Confirmation: Gilbane**
- **Vladimir Vélez (Lilly Bio-Carolina)**
- **Dr. Isaac Rivera (Lilly API - Guayama)**
- **Mabel Febres(Lilly Phar-Carolina)**
- **Dr. Erwin Alvarez (P&G)**
- **Thomas Navedo (Pfizer-Carolina)**
- **Grisell Quiles (BD Bioscience)**
- **José Torrens (Caribbean Const. Co.)**
- **Eric Sánchez (Ortho Pharm/JnJ)**
- **UPR Representatives**
- **Private University Representatives**
- **Dr. James Pérez - PRIDCO**

INDUNIV Research Cycle

EXPECTANCIES / CURRENT STATUS OF THE PROCESS

- Create the Formation of Teams Within Each Company To Procure The Generation of Areas/Topics of Interest for Research (Total Vision of Needs).
- Promote an Opportunity for Interaction/Participation Between Industry Member Scientists/Representatives with Academia Scientists (PI's & Co-I's) to Get Acquainted of Industry Areas of Interest/Needs Towards Applied Research.
- ✓ **Generate Areas & Topics of Interest, Set Priorities**
- ✓ **Identify Contacts & Prepare Abstracts for Topics Selected**
- Obtain Feedback from Industry and Academia About Ways to Improve The Process and Enhance Interest/Participation

Projects Approved 2000

PI's: Dr. N. Mehta (UPR-M Chem. Eng.) and Dr. Samuel Hernández (UPR-M Chemistry Dept)

G-98-01 "Smart Optics-Coupled Spectroscopy (FOCS) for Pharmaceutical Cleaning Validation"
The grant corresponds to the amount of **$19,068** as per the funds requested in the budget for the project in its **third year.**

PI: Dr. Rodolfo Romañach (UPR-M Chemistry Department)

P-00-08 "Development and Validation of Near Infrared Spectroscopy as a Tool for Blend Uniformity Assessment and Optimization"
The grant corresponds to the amount of **$41,552** as per the funds requested in the budget for the project for its **first year.**

PI: Dr. Carlos Velázquez (UPR-M Chem Eng.)
G-99-02 "Modeling and Automation of a Fluid Bed Dryer for Automatic Determination of End Points of Pharmaceutical Granulation's"
The grant corresponds to the amount of **$45,736** as per the funds petitioned in the budget for the project in its **second year**.

Total Awards: $106,356

Projects Sponsored / Funded

2001-2002	2002 - 2003	2003- 2004
G-00-08 - "Development and Validation of Near Infrared Spectroscopy as Tool for Blend Uniformity Assessment and Optimization" Dr. R. Romañach – (2000 : $41.6K) **Awarded $45.7K**	**G-00-08 - "Development and Validation of Near Infrared Spectroscopy as Tool for Blend Uniformity Assessment and Optimization"** **PI: Dr. R. Romañach** **Awarded $49.2K**	**G-00-08 - "Development and Validation of Near Infrared Spectroscopy as Tool for Blend Uniformity Assessment and Optimization"** **PI: Dr. R. Romañach** **Awarded $10.5K**
G-99-02 "NIR Technology for the Automation of a Fluid Bed Dryer for Automatic Determination Humidity End Points of Pharmaceutical Granulation's - Dr. Carlos Velázquez – Awarded **$64.5K**	**G-02-02 – "A More Environmentally Friendly Route to Benzazoxines" PI: Dr. Coprnelis T. Vlaar** **Awarded: $15K**	**G-03-01 "In Line Monitoring and Control in Protein Crystallization"** **PI: Dr. R.Romañach** **Awarded $50.1K**
	G-02-01 - "Preventing Occupational Injuries through Engineering Designs Based on Anthropometric Analysis of Puerto Rican Workers" by Dr. Lida Orta Awarded: $38.5K	**G-03-03 "NIR Technology for Monitoring Fermentation Process Conditions and End-Points" PI: Dr. L. Saliceti** **Awarded: $39.4K**

Projects Sponsored / Funded

2003-2004	2004 - 2005	2005- 2006
G-00-08 - "Development and Validation of Near Infrared Spectroscopy as Tool for Blend Uniformity Assessment and Optimization" **PI: Dr. R. Romañach** **Awarded $10.5K**	**G-03-01 "In Line Monitoring and Control in Protein Crystallization"** **PI: Dr. R.Romañach** **Awarded $51.31K**	**G-03-01 "In Line Monitoring and Control in Protein Crystallization"** **PI: Dr. R.Romañach** **Awarded $21K**
G-03-01 "In Line Monitoring and Control in Protein Crystallization" **PI: Dr. R.Romañach** **Awarded $50.1K**	**G-03-03 "NIR Technology for Monitoring Fermentation Process Conditions and End-Points" PI: Dr. L. Saliceti** **Awarded: $48.67K**	**G-03-03 "NIR Technology for Monitoring Fermentation Process Conditions and End-Points" PI: Dr. L. Saliceti** **Awarded: $45 K**
G-03-03 "NIR Technology for Monitoring Fermentation Process Conditions and End-Points" PI: Dr. L. Saliceti **Awarded: $39.4K**		**G-05-01 "Modeling and Optimal Control of the Mixing and Granulation Processes"** **PI: Dr. Carlos Velazquez** **Awarded: $34K**

Projects Sponsored / Funded

2006- 2007	2007 – 2008	2008- 2009
G-05-01 "Modeling and Optimal Control of the Mixing and Granulation Processes" Second Year of Award PI: Dr. Carlos Velazquez Awarded: $75K	G-05-01 "Modeling and Optimal Control of the Mixing and Granulation Processes" Second Year of Award PI: Dr. Carlos Velazquez Awarded: $60K	G-09-01 Development of Carbon Dioxide Supercritical Fluid Granulator First Year of Award PI: Dr. David Suleiman (UPR-M) Awarded: $40K
G-06-01 "Rheological Characterization and Modeling of Gelatin Formulations" PI: Dr. Aldo Acevedo Awarded: $25K	G-06-01 "Rheological Characterization and Modeling of Gelatin Formulations" PI: Dr. Aldo Acevedo Awarded: $40K	G-09-02 "Extrusion of Biodegradable Polymeric Film Strips with Embedded Solid Particles" First Year of Award PI: Dr. Aldo Acevedo (UPR-M) Awarded: $30K
		G-09-03 "pH Sensitive Chitosan Alginate Hydrogel with Adjustable Mechanical Resistance and their Application in Drug Delivery" First Year - Dr. Yang Li (UPR-M) Award: $30K
	Total Funding for 12 Projects Research Cycles since 2000 thru 2009 $920K	RESEARCH CYCLE On-Going Projects

Projects To be Considered for Sponsoring / Funding

2009- 2010 **Research Cycle** **Proposal Review & Funding** **May 2010**		
▪ **Three On-Going Projects Being Submitted for Renewal of Funding**		
New Proposal **P-10-01 "Design and Development of In situ Photocured Tablet Coatings"** – Dr. L Sievens (UPR-RCM)		

Proposals Submitted for Review & Funding 2009 – 2010 Research Cycle (May 2010 Mtg)

Proposal Title	Project #	Principal Investigator	Category or Code	Amount Being Petitioned
1. Development of Carbon Dioxide Supercritical Fluid Granulator	P-09-01	Dr. David Suleiman (UPR-M)	Process Development	**$40K**
2. pH Sensitive Chitosan Alginate Hydrogel with Adjustable Mechanical Resistance and their Application in Drug Delivery	G-09-03	Dr. Yang Li of UPR-M & (Dr. Bo Hu Univ. of Minnesota)	Formulation Research	**$30K**
3. Extrusion of Biodegradable Polymeric Film Strips with Embedded Solid Particles"	G-09-02	Dr. Aldo Acevedo-Rullan (UPR-M)	Process Development	**$40K**
4. Design and Development of In situ Photocured Tablet Coatings	P-10-01	Dr. Lucas Sievens (UPR-RCM)	Manufacturability	**$40K**
			Total requested: $150K	
			Money Available: $100K	

PROJECT ABSTRACTS

Project G-09-01

Summary

This investigation proposes the development of a supercritical fluid (SCF) carbon dioxide granulator. The study will focus on the experimental configuration to improve on the mixing and product integrity using SCF CO2 only. Narrow particle size distribution (PSD), better mixing and more homogenous structures can be some of the advantages of this process over conventional processes. However, in addition to the technical benefits of this investigation, the process can be faster, since it will overcome the need for an additional drying step. The first step of this project will be to prove the feasibility of this process. During the following years additional granulation will be performed on unique combinations of drugs-filler providing alternative options for Puerto Rico pharmaceutical companies, or even products that are in the pipeline for future deployment.

Intellectual Merit: The critical objective of the proposed work is to understand the solution behavior of a family of complex, but promising, multi-component SCF systems. The combination of the phase equilibria and mass-transport tuning with process conditions (*e.g.,* pressure, temperature and decompression rate), and its impact in the nucleation and growth model will significantly improve our understanding of the competing entropic and enthalpic effects in solution behavior of SCF systems. In addition, this study will represent, to the best of our knowledge, the first time ever that a SCF CO2 granulator is used to mix solid particles of pharmaceutical interest with the intention of obtaining a more efficient and dried granulated product. The understanding of solution behavior will be used to explain the resulting material properties experimentally-observed for the resulting granulated product.

Broader Impact: From a research perspective, the ultimate objective of the proposed work is to develop alternative mixing processes that can produce cleaner and of more-uniform drugs, while replacing environmentally-undesirable or energy-intensive solvents that are currently used in conventional processes.

Project G-09-02

- The aim of project is to study the feasibility of **continuous production of fast-dissolving edible films loaded** with solid particles by the **extrusion processing**. Portability, precise dosing, better intake, and faster bioavailability are amongst the advantages of this novel drug delivery method. Biopolymers are ideal candidates as main structural agents for this application, due to their gelling capacity, immobilization capacity in the gel network and inherent flexible processing through existing manufacturing technologies, such as extrusion, perfected in the polymers and coating industries. Flow properties determine material gelling capacity, flow behavior, and capacity as a suspending medium. Dispersion of solid particles into a polymer solution may increase the effective viscosity of a solution, which may increase the stability and loading capacity, yet, it may be detrimental for network formation (i.e. gelation). Similarly, the extrusion process may help dispersion but destroy the polymer network. Thus, it is critical to identify formulation-processing-film property relationships to optimize and design better fluid formulations.

Year 1

- Determine the effect of solid particle dispersions on the flow properties of biopolymer matrices.
- Determine the effect of extrusion processing parameters on the homogeneity and size of solid particles embedded in biopolymer matrices.

Project G-09-03

Oral drug delivery to the gastrointestinal (GI) tract is heavily researched and commercialized for various pharmaceuticals with different delivery systems. The USP dissolution tests are commonly used to simulate gastrointestinal (GI) conditions; however, in vivo drug release for hydrogel-type tablets was found very different from in vitro dissolution tests, in some cases much faster than expected. The lack of in vivo–in vitro correlation is possibly caused by the mechanical stress, received by the peristaltic movement of the GI wall. Recently, an innovative in vitro stomach system was developed at Food Engineering Department at UC Davis, which provides and monitors various mechanical forces present in the human stomach acting on food samples and drug tablets. Based on PI's years of research experience on chitosan alginate hydrogel system, adding another polymer such as ethyl cellulose can significantly increase the drug release behavior, possibly due to the better binding of the drug to the polymer matrix and better mechanical strength of the gel beads. This project, which incorporates this new food digestion model into current oral drug delivery systems, will explore the method to modify the mechanical resistance of the chitosan alginate hydrogel drug delivery matrix and their effect on the behavior of drug release in human stomach. The results will help explain the common in vitro-in vivo disintegrity for current hydrogel types of oral drug GI delivery system, and will also help develop a standard procedure for across-the-board in vitro release research from oral drug delivery systems. The hypothesis of the project is: considering the mechanical forces into current USP dissolution method, the in vivo oral drug release behavior will be able to be estimated with in vitro experiments; and innovative drug release matrix can be designed with different mechanical resistance to deliver drug with precise control to different people although they have different stomach strength during the digestion. The project will also develop the innovative design of the chitosan alginate as a model drug delivery system to target different customers based on their different stomach strength and future research can be developed in collaboration with the commercial pharmaceutical companies.

Specific objectives include: 1) Study the capability of the chitosan alginate hydrogel to resist mechanical force present in human stomach by applying the food digestion model developed by UC Davis to the drug release system; 2) develop method to modify the mechanical resistance of the hydrogel and test its drug release behavior in the food digestion model; 3) study the interaction of food and drug delivery matrix and provide the design suggestions on the customer oriented drug delivery system.

Project Proposal (P-10-01)

The aim of this work is to study, develop and optimize the film coating formation of tablets in the utilization of photocuring. It is expected that by using photopolymerization a more economically feasible and environmentally safe process will be obtained

The short term objective is to prove the feasibility of photocured coating of pharmaceuticals by using FDA approved monomers. The mid-term objective is to develop a library of monomers, including biodegradable monomers, and study their possible use as polymer membranes in pharmaceutical products. The long term research is to develop a prototype for large scale photocuring coating in collaboration with pharmaceutical companies.

The results obtained from the research and education tasks will provide scientific basis for new technology development and will have a positive impact in the pharmaceutical industry by fulfilling some of their research needs and enhancing the educational background of future professionals.

Projects Recommended for Funding
2009 – 2010 Research Cycle

Proposal Title	Principal Investigator	Topic # / Category or Code	Proposal #	Amount Recommended
Renewing Project Awards				
Development of Carbon Dioxide Supercritical Fluid Granulator	Dr. David Suleiman (UPR-M)	Process Development	G-09-01	$40K
Extrusion of Biodegradable Polymeric Film Strips with Embedded Solid Particles"	Dr. Aldo Acevedo-Rullan (UPR-M)	Process Development	G-09-02	$30K
New Project Award				
Design and Development of In situ Photocured Tablet Coatings"	Dr. Lucas Sievens (UPR-RCM School of Pharmacy & Pharmaceutical Sciences	Manufacturability	G-10-01	$30K
Funding Not Renewed				
pH Sensitive Chitosan Alginate Hydrogel with Adjustable Mechanical Resistance and their Application in Drug Delivery	Dr. Yang Li (UPR-M) / Dr. Bo Hu (Univ of Minnesota)	Formulation research	G-09-03	Not Funded; Will be invited to present at the next cycle

SAC Agreements & Path Forward

- Suggested to develop a matrix to try to collect information about the impact of the program at least during the period of 2000-2010. It is understood that the efforts towards gathering and documenting this information will demonstrate the value added contributions of the SAC and its research cycle.
- The projects as evaluated and rated will be recommended for funding provided the money is available from UPR-Central system.
- Next meeting will be coordinated for the end of August or beginning of September. The tentative agenda will consider the points annotated below.

  ** Keynote speaker (suggested in the area of translational research, but it is open for suggestions)

  ** Presentations by the PI's and the opportunity to have a break out session to form the different QST in support of the projects

  ** Presentation about the R&D Cluster

  ** Review the topics received and agreed which ones to include for the next Research Cycle "Call for Proposals"
- The meting will be a one day activity (9:00 AM – 3:00 PM) to be held in one of the member companies located in the Vega Baja – Manatí– Barceloneta area.

Impact of SAC Program
Outcomes Metrics: Value Added Contributions

Efforts Will Be Made to Gather this Information From PI's Provided Records Have Been Kept

PROJECT NUMBER & TITLE	INVESTIGATOR (PI)	TOTAL INVESTMENT	VALUE ADDED				
			Patent (s)	Publications	Graduates #'s BS / MS	Destination Acadimia or Industry	Other Grants

2010-2011 TIMELINE for RESEARC CYCLE

Milestones	**Date**
Selection of Topics and Abstracts – Contact Person	
Posting of Topics and Abstracts at Various University Campuses	
Cutoff Date or Deadline To Submit Proposals	
SAC Meeting to Select Proposals To Be Invited For Presentations to SAC	
Presentations To SAC and Final Selection Of Projects To Be Recommended For Funding	
Approval by INDUNIV Board & Announcement of Awards	