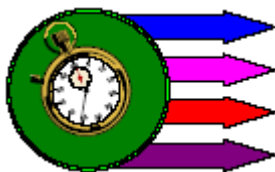


# Sustained Delivery

February 2009



## Newsletter of AAPS Modified Release Focus Group

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### Newsletter Editor's Note

*Dr. Elanor Pinto*

Welcome to the 1<sup>st</sup> Edition of the MRFG Newsletter for 2009. This issue will update you on the highlights of the Annual AAPS Meeting and the Arden Conference. Vishal Sachdeva, Anushree Herwadkar, and Lipika Chablani will brief over current *enteric coatings* for modified release. In addition, this edition will review current books on oral dosage forms. Alex Z. Liu, Banner Pharmacaps, has provided us a minireview on softgel capsules application. Finally, we all welcome Joe Reo as the new Chair of the MRFG Steering Team and congratulations to John Crison as the new Chair-Elect. A special thanks to Avi Thombre for all his initiative and hard work in leading the MRFG Steering Team last year.

The MRFG Steering Team is always looking for volunteers.

If your talents and interests move you to editing a newsletter, please contact me ([epinto@ashland.com](mailto:epinto@ashland.com)). Let **Sustained Delivery** be your tool for mining the golden knowledge of MR technology.

### Chair's Corner

*Dr. Joe Reo*

As the incoming Chair for the Modified Release Focus Group (MRFG), a big thanks to all of the members for electing me. It will be my honor to serve this prestigious focus group as the Chair. I certainly have some big shoes to

fill. Dave Wallick, the Past-Chair of 2008, has been an overwhelmingly positive force and a stalwart of excellence. Under Dave's leadership, the focus group has made significant contributions, including the expansion of the Newsletter and initiation of the discussion board, all fantastic communication instruments. Avi Thombre, the Chair for 2008, has also continued the tradition of excellence. Under Avi's leadership, the focus group has raised the bar for focus-group-sponsored programming. Avi has expanded the reach of programming by co-leading a Short Course in 2007 at AAPS Annual Meeting with the Controlled Release Society. Avi supported the first ever focus-group sponsored webinar led by Hannah (Hye-Ok) Choi in 2008. He also led the Steering Committee to establish the first-ever focus-group-sponsored Student Travelship to the AAPS Annual meeting in 2008 (Schering-Plough Consumer Healthcare provided financial support).

I am happy to announce that John Crison from Simulations Plus is the Chair-Elect. John served in the MRFG programming committee last year and as Chair-Elect, he takes on the duties as head of MRFG programming for 2009. Get ready for a strong year for programming with John at the helm. I am thrilled to have the opportunity to work closely with John to co-lead the MRFG this year.

Next, a little about myself. I have 30 years experience in the pharmaceutical industry with several Rx and OTC companies. I am currently a Research Fellow at Schering-Plough Consumer Healthcare in Memphis, Tennessee. I am the technical lead for several brands/projects, lead a small group of scientists, work closely with Business Development and Marketing to identify market opportunities for the OTC business unit, and oversee the formulation portions of the CMC sections for regulatory submissions. Previously, I have worked at Pfizer/Pharmacia Rx division in Kalamazoo, Michigan and McNeil Consumer Healthcare in Fort Washington, New Jersey. My

professional passions include merging technology with business needs and developing junior and mid-level scientists.

I was personally touched by the enthusiastic turn-out for the MRFG Business Meeting during the AAPS Annual meeting in November. The turn-out reflected one of the responses we obtained from the 2008 MRFG member survey. There are a core group of members who want to get more involved in MRFG activities. From the fantastic turn-out, we have added several individuals to the Steering Committee Membership (see list at the end of the Newsletter). Part of my mission this year is to try to tap further into untapped potential to accomplish the 2009 goals. More about this in future Newsletters.

I'll close with few words about 2009 Goals. A list of the goals is published at the end of this Newsletter. I have carried-over several of the successful elements that have been the mainstay of the MRFG, e.g. Student Outreach and Programming. In addition to continuation of the past excellence, I would like to drive an increase in dissemination of scientific information relevant to the field of modified-release technology. We seek short articles for the Newsletter from all of the members, with special emphasis on excipients used for modified-release dosage forms. In addition, we are seeking reviews, mini-reviews and featured articles to be published in a yet to be determined journal. I will elaborate on this topic next time.

Thank you all for a successful 2008. We look forward to a 2009 that will be filled with even more success and contributions to enhance the field of modified release technology.

### **Annual AAPS Meeting**

The 2008 Annual AAPS Meeting was held down south in Atlanta, Georgia from November 16<sup>th</sup> to the 20<sup>th</sup>. Scientists worldwide came to debut their breakthrough research and discuss high-interest topics. The Controlled Release Society (CRS) collaborated with AAPS on Saturday and Sunday's workshop "Critical Variables in *In Vitro* and *In Vivo* Parenteral Product Performance." Short Courses such as Sunday's "Harnessing Drug-Polymer-Excipient Interactions for the Rational Design of Modified Release Formulations" drew a lot of interest.

Last year's conference had a good share of interesting speakers and innovations. Past President Dr. Karen Habucky said her farewells and welcomed in current President Dr. Patrick DeLuca. The Keynote Address "Challenges of Pediatric Drug Development" by Dr. William E. Evans was enticing. AAPS also attracted companies showcasing their novel technologies such Philip's iPill which

can be used in diagnostics and treatment of GI diseases. The iPill is a specialized capsule which utilizes precise pH monitoring to determine the location of pill for targeted drug delivery.

To those who couldn't attend the conference, PharmTech.com has video interviews showcasing latest pharmaceutical developments live from the 2008 AAPS conference. Coverage includes speakers discussing topics such as "Liquid-Filled Hard Capsule Technology" and "Nanotechnology in Pharmaceuticals." In addition, sponsors of the conference highlight their novel or popular products such as Dow's OPTIM<sup>TM</sup> Synthetic Glycerine or Croda's Superfined<sup>®</sup> excipients. To view these videos, visit the PharmTechTV website (<http://pharmtech.findpharma.com/pharmtechtv>) and look under the link 'AAPS 2008.'

The 2009 Annual AAPS Meeting will be held in sunny Los Angeles, California this coming November 8-12. Look forward to seeing you there.

### **2009 Arden Conference**

*Dr. Steve Howard*

#### **Sterile Controlled Release Dosage Forms – Development and Technology**

The MRFG co-sponsored this past 2009 Arden Conference. The title for this year's conference is Sterile Controlled Release Dosage Forms –Development and Technology. The conference was held at the Thayer Hotel in West Point, NY, February 1-6, 2009. This program was designed to update pharmaceutical scientists on the latest technologies in developing sterile controlled release products for both small and large molecules. The program discussed the latest developments in, ocular, and parenteral (including implants) controlled release products as well as sterile dermal and dental products. Detailed presentations discussed new technologies, material selection, development aspects, testing and release and manufacture of these products. In addition, the conference had detailed discussion on sterilization, testing and stability of these dosage forms. Each topic included lectures from experts in the field followed by workshops and discussion groups.

Despite the low attendance due to the economy, the meeting was a great success. The speakers were well received and all the speakers generated questions and discussions. The Sessions were attended by all present whom actively participated in the discussions. Because of the high interest in the discussions, the sessions were long starting at 9AM and ending at almost 10PM. The groups' enthusiasm never seemed to waver. I believe for all those who attended this meeting, it was an extremely worthwhile

experience. In fact, many stated they were glad they participated and were sorry more individuals were not able to attend this excellent conference.

### Tech Corner: Enteric Coatings

Vishal Sachdeva, Anushree Herwadkar, and Lipika Chablani  
Mercer University

Enteric coatings find a variety of applications in solid dosage forms. By acting as a barrier that resists dissolution in the gastric pH, it enables us to increase the bioavailability of oral drugs. At the same time, it can provide localized drug delivery to the gastrointestinal tract.

Liu, Fang; Lizio, Rosario; Meier, Chistian; Petereit, Hans-Ulrich; Blackey, Peter; Basit, Abdul. A novel concept in enteric coating: A double coating system providing rapid release in the proximal small intestine. *Journal of Controlled Release* (2009), **133**(2), 119-124.

Enteric coatings can be used to protect steroids using double-coatings. Fang Liu *et. al.* introduced the double-coating concept and compared the conventional single coating of Prednisolone to that of the double-coated tablets. Single enteric coating of tablets may lead to a delay in the *in vivo* tablet disintegration. Thus, drug release would occur in the large intestine and may be detrimental for drugs having an absorption window in the small intestine. A double coating offers better release and patient compatibility than a single coating. Eudragit was used as the external coat along with Triethyl citrate. The inner coat consisted of Triethyl citrate-Eudragit neutralized by 1M NaOH with or without addition of organic acid. The dissolution of the coatings was a function of ionizable carboxylic acid groups in the polymer. Ionization was achieved by addition of NaOH which converts free acid to the salt form. Addition of organic acid, such as citric acid in the outer coating results in formation of a buffer (eg: citric acid and sodium citrate). The enhanced solubility of the double coated tablets was thus, a result of the increased ionic strength and buffer capacity. Double coatings offer a promising approach for localized delivery to the small intestines in comparison to the conventional single coating methods.

Ibekwe, V.C.; Khela, M.K.; Evans, D.F.; Basit, A.W. A new concept in colonic drug targeting: a combined pH-responsive and bacterially-triggered drug delivery technology. *Alimentary Pharmacology and Therapeutics* (2008), **28**(7), 911-916

In this study, two approaches for colonic drug targeting have been combined. A coating mixture consisting of Eurylon VII and Eudragit was applied by spray drying on the core tablets. Eurylon is a polysaccharide degraded specifically by the colonic bacteria and Eudragit is a pH-

sensitive polymer that dissolves at the high pH of the colon. The combined pH and bacterial approach made a foolproof system for colon specific drug delivery. Clinical studies were carried out on healthy male volunteers to check the effectiveness of such a system. The authors concluded that successful delivery can be achieved with the pH-bacterial dual approach. It can find potential application in treating diseases of the colon such as ulcerative colitis and inflammatory bowel disease.

Bendas, Ehab.R.; Ayres, James W. Leaky enteric coating on ranitidine hydrochloride beads: Dissolution and prediction of plasma data. *European Journal of Pharmaceutics and Biopharmaceutics* (2008). **69**(3), 977-985

The application of leaky enteric coatings was investigated on the drug pellets with variations in formulation components such as amounts of lactose, PEG 8000, Span 60, and Tween 80. From the *in vitro* studies, it was reported that "all formulations completely released the drugs within 30 min after changing dissolution medium to phosphate buffer of pH 6" suggesting improved bioavailability of the drug ranitidine hydrochloride due to the improved drug delivery method. In post *in vitro* studies, computer simulations were employed to predict plasma-concentration-time profiles of immediate-release formulations. Lastly, it was concluded that leaky enteric coated formulations can be sorted for delivering clinically effective doses of drugs like Ranitidine and yet be expected to maintain their bioavailability.

Rozhon, Edward J.; Khandwala, Atul S.; Sabouni, Akram; Balwani, Gul P.; Chan, Jody Wai-Han; Sesin, David F. Method of Treating Secretory Diarrhea with Enteric Formulations of Proanthocyanidin Polymer. Patent No.: US 7,341,744 B1. Date of Patent: Mar. 11, 2008.

Pharmaceutical compositions containing a proanthocyanidin polymer composition which are useful for the treatment and prevention of secretory diarrhea are provided. The invention specifically relates to pharmaceutical formulations of a proanthocyanidin polymer composition which has been isolated from a *Croton* spp. or a *Calophyllum* spp. In particular, the invention relates to a formulation of a proanthocyanidin polymer composition which protects the composition from the effects of stomach acid after oral administration, particularly to those formulations which are enteric coated. The invention also relates to methods of producing a directly compressible proanthocyanidin polymer composition, as well as compositions containing the directly compressible proanthocyanidin polymer composition.

## Book Reviews: Oral Dosage Forms

Zheng, Jack. *Formulation and Analytical Development for Low-Dose Oral Drug Products*. (2009). ISBN-10: 0-4700-5609-6.

There are unique challenges in the formulation, manufacture, analytical chemistry, and regulatory requirements of low-dose drugs. This book provides an overview of this specialized field and combines formulation, analytical, and regulatory aspects of low-dose development into a single reference book. It describes analytical methodologies like dissolution testing, solid state NMR, Raman microscopy, and LC-MS and presents manufacturing techniques such as granulation, compaction, and compression. Complete with case studies and a discussion of regulatory requirements, this is a core reference for pharmaceutical scientists, regulators, and graduate students.

McGinity, James; Felton, Linda A. *Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms, Third Edition (Drugs and the Pharmaceutical Sciences)*. (2008). ISBN-10: 0-8493-8789-2.

This book provides an in-depth synopsis of the applications and the physical-chemical properties of aqueous-based polymer-coated pharmaceutical dosage forms. Thoroughly updated and expanded, this new **3<sup>rd</sup> edition** provides the latest information on dosage, forms, film defects, and polymer characterization. The book overviews the interaction of drugs with functional polymers, the influence of processing parameters on coating quality, the stabilization of polymeric film coats, plasticizers and their applications in pharmaceutical coatings, adhesion of polymeric films to solid substrates, and basic properties of latex and pseudolatex colloidal dispersions.

Augsburger, L.; Hoag, Stephen W. *Pharmaceutical Dosage Forms: Tablets, Third Edition (Three – Volume Set)*. (2008). ISBN-10: 1-4200-6345-6.

This book is a comprehensive resource of the design, formulation, manufacture, and evaluation of the tablet dosage form. The ultimate goal of drug product development is to design a system that maximizes the therapeutic potential of the drug substance and facilitates its access to patients. With over 700 illustrations, the series guides pharmaceutical scientists and engineers through difficult and technical procedures in a simple easy-to-follow format. Volume 1, *Unit Operations and Mechanical Properties*, examines the fundamental physical and chemical processes that the different unit operations use and applies this knowledge to the discussion of the varying unit operations and processes. Volume 2, *Rational Design and Formulation*, focuses on the rational design and formulation of a tablet and includes chapters with practical

illustrations and formulation examples. The final volume, *Manufacture and Process Control*, completes the comprehensive resource.

Rathbone, Michael J.; Hadgraft, Jonathan; Roberts, Michael S.; Lane, Majella E. *Modified-Release Drug Delivery Technology, Second Edition*. (2008). ISBN-10: 1420053566.

Because of the slow and costly process of developing new blockbuster drugs, pharmaceutical scientists are increasingly charged with reformulating existing drugs in order to expand a company's market opportunity and to sustain company growth. This presents an opportunity for formulation scientists to innovate and develop novel drug delivery systems to extend the commercial life of existing drugs. Divided into two volumes, this **Second Edition** describes the anatomical, physiological, pharmaceutical, and technological aspects of oral, colonic and rectal, ocular, oral mucosal, dermal and transdermal, nasal, vaginal, and pulmonary delivery routes, providing insight and critical assessment of the many available and emerging modified release drug delivery systems for their current and future value.

Qiu, Yihong; Liu, Lirong; Zhang, Geoff; Chen, Yisheng. *Developing Solid Oral Dosage Forms: Pharmaceutical Theory & Practice*. (2008). ISBN-10: 0-444-53242-0.

This book provides an up-to-date comprehensive overview of solid product development. It dwells into preformulation investigation, formulation/process design, scale up, and regulatory aspects for rational oral dosage technologies from a global perspective. Examples and/or case studies in product development are included in every chapter.

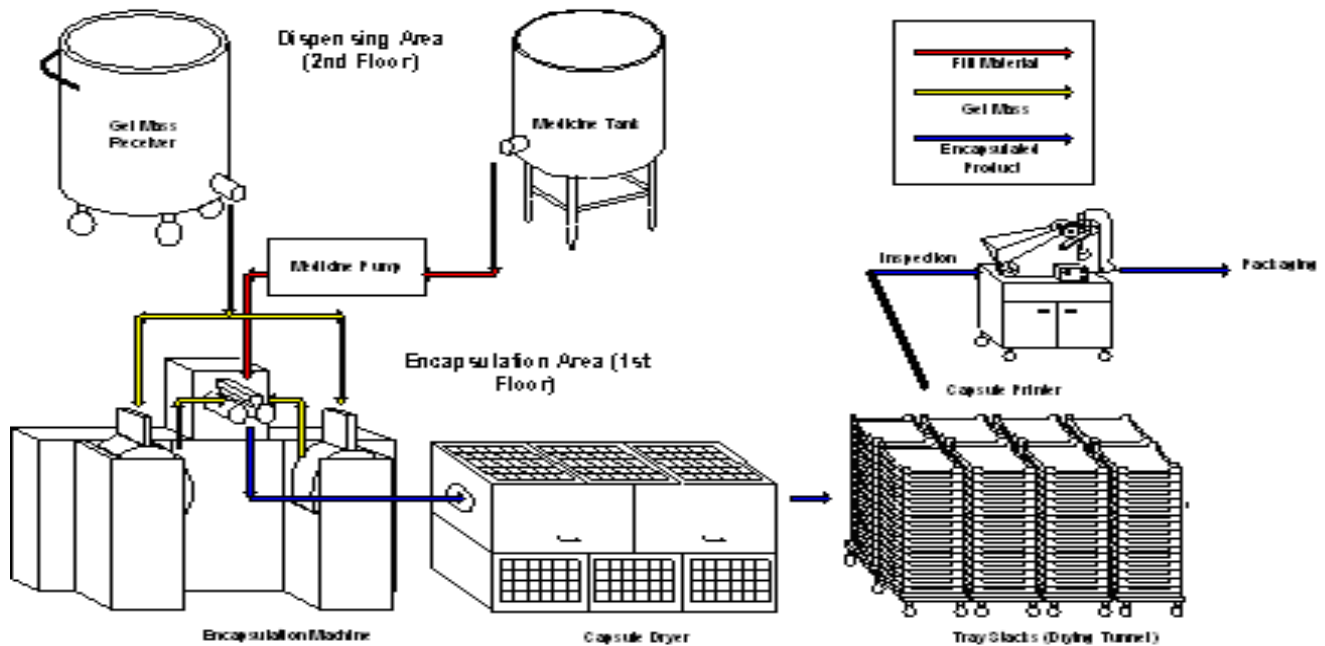
### Special Minireview:

#### Application of Softgel Capsules

*Alex Z. Liu, Shingai Majuru, Dana Toops, and Aqeel Fatmi  
R&D, Banner Pharmacaps*

Soft gelatin capsules (SGC) are traditionally made from gelatin. Gelatin is extracted from collagen by hydrolysis using acid or alkaline treatment process. Type A gelatin is generated using an acid treatment process while Type B gelatin is generated using an alkali treatment process. The dosage forms using gelatin are two-piece hard gelatin capsules, soft gelatin capsules, tableting, tablet coating, tablet enrobing, granulation, and microencapsulation.

In the soft gelatin manufacturing process, membranes made from gelatin are used to encapsulate liquid or semi-solid fill (oil based, or non-aqueous based, with active ingredients being dissolved or suspended), to produce *pharmaceutical* or nutraceutical products enclosed in a shell. Soft gelatin capsules can encapsulate concentrated active ingredients in a cost effective way. Besides, they



**Figure 1.** Manufacturing Process Overview (Courtesy of Banner Pharmacaps Inc., with permission to use).

offer great capacity of masking of unpleasant odors and tastes. It is of no surprise that SGC are widely used for the delivery of Vitamins, fish oil, and numerous other naturally-derived products. Soft gelatin capsules are traditionally preferred by consumers over other dosage forms since they are perceived as being easy to swallow and have a rapid onset of action<sup>1</sup>.

One of the most interesting aspect of SGC in pharmaceutical field derives from their ability to incorporate liquid-based (or low melting point) pharmaceutical excipients (solvent, and surfactant) to enhance bioavailability of poorly water-soluble drugs. This gives rise to the potential of using this technology to reformulate existing drugs and new chemical entities for improved biopharmaceutical characteristics. For example, upon exposure to aqueous medium, the Neoral formulation SGC<sup>2</sup> turns into a microemulsion resulting in improved bioavailability and lower dosing.

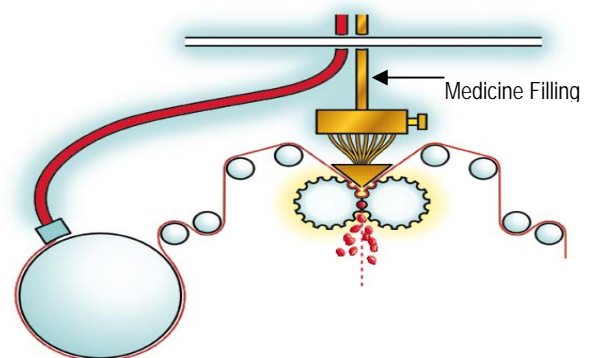
The current industrial soft-gel encapsulation process was invented by [R.P. Scherer](#) in 1933, where a rotary die is used to produce the capsules. The filling is accurately delivered to the void of the die to produce inflated capsules. This method reduces wastage and improves efficiency and is the standard process to yield capsules with highly repeatable and accurate dosage<sup>3</sup>.

The schematic process flow of manufacturing SGC is depicted in Fig. 1. Gel preparation is the first step where gelatin, a plasticizer, and adequate quantity of water are mixed at heated conditions (e.g., 70 °C) to produce

homogeneous and a highly viscous liquid. When fed to chiller drums at a temperature well below the gelling point of gelatin, thin membranes (or ribbons) are made. The ribbons are pulled through a rotary die, where the medicine filling and encapsulation take place. Capsules are then sent to a tumbler drier to remove a considerable amount of water to reduce the stickiness. Further drying takes place in the tray drying tunnel, which is followed by inspection for defects before sending for packaging.

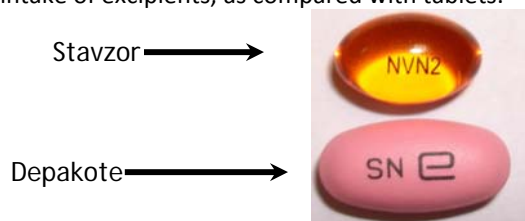
The most critical step in soft-gel capsule manufacturing is the encapsulation step. The medicine filling (in yellow color) is injected between two ribbons (in red color) while the sealing of capsules take place in the rotary dies, as illustrated in Fig. 2.

**Figure 2.** Encapsulation Process (Courtesy of Banner Pharmacaps Inc., with permission to use).



Commonly used liquid and semi-solid excipients are generally suitable for SGC formulations. Reference 10 provided a useful guide of the up-to-date list of suitable excipients.

Exploring the unique property of SGC in modified release products is of great importance for the future of pharmaceutical industry<sup>4</sup>. A breakthrough was the recent FDA approval of Stavzor®-Valproic acid DR, liquid filled SGC, which is competing with Depakote DR (enterically coated tablets of divalproex sodium). Valproic acid or its salt form (divalproex sodium) is known to cause stomach upset, which prompted the development of Depakote DR. Banner Pharmacaps Inc. (Highpoint, NC) developed a patent-pending (Tradename: EnteriCare) proprietary shell composition with enteric properties built within. It produces DR drug products by filling the liquid valproic acid encapsulated in the novel shells. The enteric property is achieved without using external coating of capsules by enteric polymer, minimizing the risk to product quality and performance of coating on top of softgel capsules (such as flaking or cracking commonly found with coated capsules). Another advantage of liquid-fill SGC is smaller than the tablet because SGC allows use of little processing aids or bio-availability enhancing excipients in the fill (as shown in Fig. 3). The benefits for patients are the ease in swallowing and less intake of excipients, as compared with tablets.



**Figure 3.** Stavzor® SGC (the clear, yellow capsule) is smaller than Depakote (the pink tablet), at the same dose of 500 mg API.

By incorporating sustained release excipients in the fill matrix, SGC can provide time release property to a wide range of drugs<sup>4, 5</sup>. Banner's patent-pending controlled-release SGC enables delivery of compounds in a sustained profile. Particularly, it has the potential to allow formulation of poorly soluble drugs with lipid-based delivery technology to enhance the absorption. The most noticeable benefit of this dosage form is its versatility to use an emulsion- or a suspension-based matrix.

The current trend of SGC formulation is to combine modified release technology with lipid-based excipients that hold the promise of delivering faster onset of effect with lower dosage, lower side effects, and less-frequency

dosing. Hence, it will continue to provide advantages not available from traditional modified release technologies, such as, tablet coating and multiple particle coating.

#### References

1. Jones III, W. J, and Francis J. J., (2000) Softgels: Consumer Perceptions and market Impact relative to Other Dosage Forms. *Advances in Therapy*, 17(5), 213-221.
2. NEORAL (cyclosporine) Soft Gelatin Capsules, USP MODIFIED (<http://www.rxlist.com/neoral-drug.htm>, date of access: December 04, 2008).
3. Capsule. Wikipedia [[http://en.wikipedia.org/wiki/Capsule\\_\(pharmacy\)](http://en.wikipedia.org/wiki/Capsule_(pharmacy))], accessed date: December 04, 2008].
4. Doran, T., and Fatmi, A., Banner Pharmacaps: From Contract Manufacturer to Innovative Drug Delivery & Healthcare Company. *Drug Delivery Technology*. 4(2) (2004).
5. Versatrol: Controlled Release Softgels (<http://www.banpharm.com/en/versatrol.asp>, date of access: December 04, 2008)

### Pulsatile Delivery

#### *Bullets of useful information*

- **Upcoming Symposium:** The 14<sup>th</sup> International Symposium on Recent Advances in Drug Delivery Systems (<http://drugdeliversymposium.utah.edu/>) will be held in Salt Lake City, Utah from February 15-18, 2009. This year's theme is "Drug Carriers: Progress Beyond Delivery."
- **Upcoming Short-Course:** "Fundamentals of Blending, Compression and Coating of Tablets and Tooling" <http://natoli.com/technicaltraining.htm> will be held in St. Charles, MO from February 24-26, 2009. The short-course is developed for individuals involved in the tablet manufacturing industry and addresses common industry pitfalls.
- **Upcoming Meeting:** "Formulating Better Medicines for Children" (<http://www.rpsgb.org/pdfs/sciconf090302.pdf>) will be held in London, England from March 2-3, 2009. The meeting will discuss issues surrounding the availability of age-appropriate formulations for the benefit of young patients.
- **Upcoming AAPS Workshop:** Scientific and Technological Advances in the Use of Lipid-based Drug Delivery Systems for Bioavailability Enhancement and Tissue Targeting ([http://www.aapspharmaceutica.com/meetings/files/142/AAPS\\_LIPIDS\\_PRELIM\\_v3.pdf](http://www.aapspharmaceutica.com/meetings/files/142/AAPS_LIPIDS_PRELIM_v3.pdf)) will be held at the Sheraton Inner Harbor Hotel in Baltimore, MD on March 10-11, 2009. The workshop

will discuss fundamental and practical aspects of formulating and manufacturing lipid-based systems.

- **Upcoming Satellite Meeting:** The CRS Satellite Meeting on ‘Oral Multi-particulate Drug Delivery Systems: Challenges and Opportunities’ ([http://www.controlledrelease.org/main/meetings/SatelliteMeetings/2009\\_03SatelliteMeeting.cfm](http://www.controlledrelease.org/main/meetings/SatelliteMeetings/2009_03SatelliteMeeting.cfm)) will be held in Vienna, Austria from March 24-25, 2009.
- **Short-Course:** ‘Principles of Solid Dosage Forms’ (<http://ce.pharmacy.wisc.edu/courseinfo/2009Solids/>) will be held at the University of Wisconsin School of Pharmacy from May 4-8, 2009. The course will provide the learner with an understanding of the underlying scientific principles governing the development of solid dosage forms.
- **Upcoming Conference:** The 17<sup>th</sup> International Congress for the Society for Aerosols in Medicine (<http://www.isam2009.com/main.cfm?cid=1333>) will be held in Monterey, CA from May 10-14, 2009.
- **Short-Course:** ‘Nanoparticles: Applications in Drug Formulation and Delivery’ (<http://ce.pharmacy.wisc.edu/courseinfo/2009Nanoparticles/>) will be held at the University of Wisconsin School of Pharmacy from May 18-20, 2009. The course will concentrate on key highlights of nanotechnology along with nanoparticles definitions and characteristics as applied to drug delivery and formulation and product development considerations.
- **Upcoming Conference:** The 2009 AAPS National Biotechnology Conference (NBC) (<http://www.aapspharmaceutica.com/meetings/biotec/bt09/index.asp>) will be held in Seattle, WA from June 21-24, 2009. Program includes topics such as the ‘Controlled Release Drug Delivery Strategies for Biotech-derived Compounds’ and ‘Novel Technologies of Drug Delivery’.
- **Upcoming Meeting:** The 36<sup>th</sup> Controlled Release Society (CRS) Annual Meeting and Exposition (<http://www.controlledrelease.org/meeting/default.cfm>) will be held in Copenhagen, Denmark on July 18-22, 2009.
- To receive regular copies of *Sustained Delivery*, the newsletter of the AAPS Modified Release Focus Group, join the MRFG ([www.aapspharmaceutica.com/inside/focus\\_groups/fgap.asp](http://www.aapspharmaceutica.com/inside/focus_groups/fgap.asp)) and sign up for the listserv ([www.aapspharmaceutica.com/inside/listserves/index.asp](http://www.aapspharmaceutica.com/inside/listserves/index.asp)) to keep current on your MRFG newsletter, *Sustained Delivery*, and other Focus Group communications.

- As a MRFG member, our Discussion Board ([community.aapspharmaceutica.com/ShowForum.aspx?ForumID=12](http://community.aapspharmaceutica.com/ShowForum.aspx?ForumID=12)) is available for your use. Start a topic, ask a question, or share your expertise for the enrichment of others and learn, share, or serve as you like. Check it out.
- **Spread the word.** Pass this newsletter issue to your friends and colleagues and encourage them to share in the information exchange and networking opportunities by joining AAPS and the Modified Release Focus Group.
- Send your questions or comments about the MRFG Sustained Delivery newsletter to the Editor ([epinto@ashland.com](mailto:epinto@ashland.com)). Your topics or contributions for the next newsletter are welcome. Let us know about:
  - Upcoming meetings of interest to the MRFG membership
  - Recognitions and awards for MRFG members
  - Your new technical or commercial MR highlights (public info only)
  - Your program ideas for future AAPS meetings

## MRFG Charter

The purpose of the Modified Release Focus Group (MRFG) is to provide a forum for scientists – representing academia, industry, and regulatory agencies – involved in the mechanistic understanding, formulation design and development, process development and scale up, and related regulatory aspects of modified release dosage forms. Modifying the release of a drug from a dosage form is desired to control the physiological site and timing of drug uptake by the body. This Focus Group will give scientists a forum to exchange ideas and share knowledge in the field of modified drug release technology.

Modified release formulation design for oral and non-oral administration routes. For an oral dosage form, modification of drug release can be achieved via mechanisms that include drug diffusion, dosage form erosion, osmosis-mediated drug delivery, and others. Particulate, matrix, and coated systems represent a major portion of the oral modified release dosage forms. Modified drug release from dosage forms is complemented by the allied processes of drug design, of dosage administration, and of membrane transport and absorption of drug to the biological site of action; discussion of these phenomena are the subject of other AAPS-sponsored Focus Groups. The MRFG develops joint programming with these other Focus Groups to offer

members comprehensive coverage of important drug delivery challenges and technologies.

## 2009 Goals and Plans for the MRFG

- Continue Student Outreach
  - Continue Student Focus in Newsletter
  - Enhance communication on major campuses
  - Continue Student Travelship to AAPS AM
- Improve dissemination of MR information
  - Partner with vendors to spotlight MR excipients in Newsletter (Oral, Parenteral, Ocular MR)
  - Work with Editor of AAPS SciTech to publish a MR research/development thematic issue in 2009
  - Write mini-reviews of interest to MRFG members (seek MRFG volunteers)
- Use website more effectively to disseminate MR information
- Continue to contribute to AAPS Programming
  - NBC and AM
  - Sponsor a webinar for 2009
  - Joint sponsorship of workshop/short course with other organizations, like CRS
- Increase involvement of MRFG membership
  - Tap into untapped membership
- Increase membership from MSE and PPB sections
  - Secondary affiliations with MRFG
  - Conduct advertising/membership drive
- Generate “Survival Guides” for Chair, Chair-Elect, and Past-Chair
  - AAPS-wide initiative for Sections and FGs

## Meet Your MRFG Steering Team Leadership

Your Steering Team is ready to meet the needs of the MRFG membership. Feel free to contact them for answers to your questions or to share your ideas for a better MRFG.

### EXECUTIVE LEADERSHIP

**Chair:** Dr. Joseph Reo  
*Schering-Plough*  
[joseph.p.reo@spcorp.com](mailto:joseph.p.reo@spcorp.com)  
Phone: 901-320-2383

**Chair-Elect:** Dr. John Crison  
*Simulations Plus*  
[John.crison@simulations-plus.com](mailto:John.crison@simulations-plus.com)  
Phone: 661-723-7723 Ext. 252

**Past-Chair:** Dr. Avi Thombre  
*Pfizer*  
[avinash.q.thombre@pfizer.com](mailto:avinash.q.thombre@pfizer.com)  
Phone: 860-441-8734

### STEERING TEAM

Dr. Esteban Bornancini  
*GlaxoSmithKline*  
[esteban.r.bornancini@qsk.com](mailto:esteban.r.bornancini@qsk.com)

Dr. Linda Felton  
*University of New Mexico*  
[lfelton@unm.edu](mailto:lfelton@unm.edu)

Dr. Alex Liu  
*Banner Pharma*  
[aliu@banpharm.com](mailto:aliu@banpharm.com)

Dr. Hye-Ok Choi  
*GlaxoSmithKline*  
[hannah.h.choi@qsk.com](mailto:hannah.h.choi@qsk.com)

Dr. Shirley Wu  
*University of Toronto*  
[Sxy.wu@utoronto.ca](mailto:Sxy.wu@utoronto.ca)

Dr. Michael A. Repka  
*University of Mississippi*  
[marepka@olemiss.edu](mailto:marepka@olemiss.edu)

Dr. Steve Howard  
*Howard Consulting*  
[jshoward.1@sbcglobal.net](mailto:jshoward.1@sbcglobal.net)

Sampada B. Upadhye  
*University of Mississippi*  
[supadhye@olemiss.edu](mailto:supadhye@olemiss.edu)

Dr. Ashlesh Sheth  
*Schering-Plough*  
[ashlesh.sheth@spcorp.com](mailto:ashlesh.sheth@spcorp.com)

Dr. Samantha Lai  
*Pharm Tamlylin*  
[samantha.lai@pharm.tamlylin.com](mailto:samantha.lai@pharm.tamlylin.com)

Vishal Sachdeva  
*Mercer University*  
[Vishal.Sachdeva@student.Mercer.edu](mailto:Vishal.Sachdeva@student.Mercer.edu)

Dr. Stephen P. Mayock  
*Catalent*  
[steve.mavock@catalent.com](mailto:steve.mavock@catalent.com)

Dr. Jian-Xin Li  
*Evonik Degussa*

Maria Nadeau  
*AAPS*  
[NadeauM@aaps.org](mailto:NadeauM@aaps.org)

Dr. Tim Cabelka  
*Dow*  
[TCabelka@dow.com](mailto:TCabelka@dow.com)

Dr. Elanor Pinto  
*Ashland Aqualon*  
[epinto@ashland.com](mailto:epinto@ashland.com)

Dr. Kevin W. Burton  
*Brookwood Pharma*  
[kburton@brookwoodpharma.com](mailto:kburton@brookwoodpharma.com)

Dr. Chungiang Guo  
*Abbott*  
[chungiang.guo@abbott.com](mailto:chungiang.guo@abbott.com)