



FORMULATION. MANUFACTURING. PACKAGING.

SEPTEMBER 2008 EDITION  
SCIENTIFIC NEWS FROM BAXTER

# INDUSTRY CONFERENCE UPDATE NEWS BRIEFS

## MEET BAXTER SCIENTISTS AT INDUSTRY EVENTS

Attendees will have the opportunity to meet scientists and executives from Baxter, a leader in parenteral contract manufacturing. Stop by the Baxter booth to learn more about the company's expertise in formulation technology, contract manufacturing and enhanced packaging.

## Highlighting Baxter's Cartridge Line 1

Baxter's BioPharma Solutions business offers a diverse parenteral manufacturing platform that includes not only syringe and vial filling, but a high-capacity, state-of-the-art cartridge filling line.

Cartridge Line 1 is fully automated and features Bausch + Stroebel filling, washing/siliconization, depyrogenation and labeling equipment as well as an Eisai inspection machine. It can maintain a filling speed of up to 18,000 cartridges per hour.

"The technology incorporated into our cartridge line reduces waste and provides for a higher degree of filling, as compared to previous cartridge production methods," said Matthew Ervin, principal engineer at Baxter.

### PRECISE FILLING

The equipment employs sensor filling technology, which allows 80 percent of the therapeutic to flow into the cartridge in a traditional manner and then uses a sensor to precisely fill the remaining 20 percent.

"With this technology, we are able to fully monitor filling quality throughout the process," said Ervin.

The equipment's two-stage filling process also reduces risk of product foaming and splashing, which helps avoid product loss.

### ENHANCED FLEXIBILITY

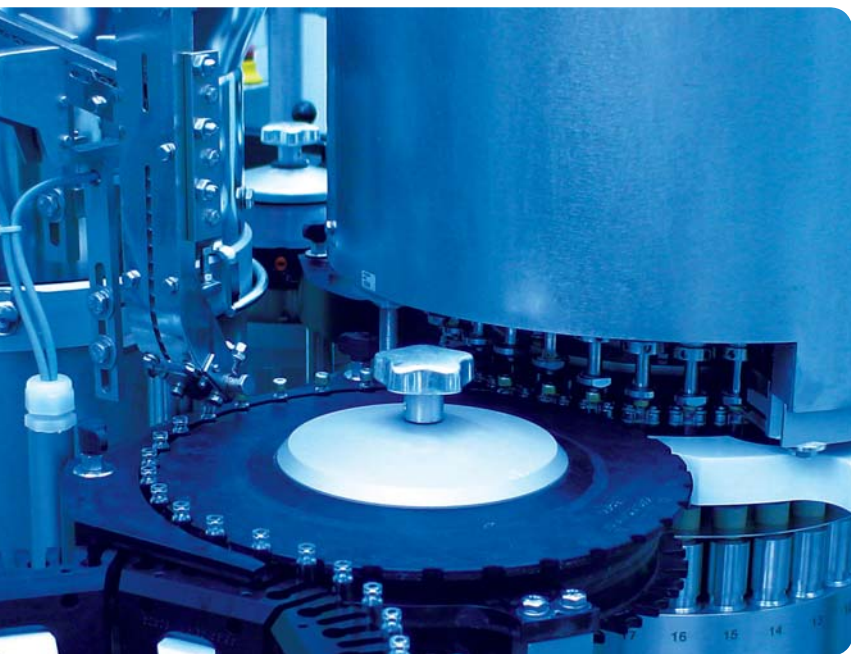
The cartridge line expands platform options for Baxter customers and accommodates a variety of product specifications, including cartridge size. The line is currently validated with 1.5 mL, 2.7 mL, and 3.0 mL Type A cartridges and can fill units that range in size from 8-14 mm in diameter and 40-90 mm in height.

The line also is capable of plunger insertion depths of up to 40 mm, with an insertion depth accuracy of +/- 0.5 mm. Labels that range from 15-80 mm in height and 20-120 mm in length can be applied.

### POSITIVE EXPERIENCE

Cartridge Line 1's advanced filling technology is just part of an ongoing effort by Baxter to provide customers with a positive experience. Ervin explains, "this facility is state-of-the-art, but it is Baxter's expertise in parenteral manufacturing and process development that can make the difference for our customers and their valuable molecules."

(NEWS BRIEFS CONTINUED ON PAGE 3)



## VISIT US AT:

INTERNATIONAL CONTRACT SERVICES EXPO (ICSE) 2008  
SEPTEMBER 30 - OCTOBER 2, 2008 | FRANKFURT, GERMANY  
MESSE FRANKFURT GmbH  
BAXTER EXHIBITING AT BOOTH #41E48

AMERICAN ASSOCIATION OF PHARMACEUTICAL  
SCIENTISTS (AAPS) ANNUAL MEETING & EXPOSITION  
NOVEMBER 16 - 20, 2008 | ATLANTA, GEORGIA  
GEORGIA WORLD CONGRESS CENTER  
BAXTER EXHIBITING AT BOOTH #1914

✦ Computational Method of Treating Kinetic Data Acquired by Using  
a pH-stat  
J.E. Kipp, S. Benton and G. Desal



## Spotlight

### SPOTLIGHT ON BRIK EYRE AND BAXTER BIOPHARMA SOLUTIONS



In January of 2008, Brik Eyre joined Baxter as general manager for the BioPharma Solutions business with global responsibility for the pharma partnering business, including the Bloomington and Halle facilities, along with enhanced packaging.

With 20 years of experience in marketing, sales, global strategy, operations, business development and general management, Brik has built an impressive career and held several senior positions with successful global healthcare leaders such as Baxter, Cardinal Health and Allegiance. He possesses a wide breadth of knowledge about the global healthcare business as well as distribution and manufacturing operations, having led sizeable organizations in multiple locations through periods of growth and business improvement.

Eyre holds an undergraduate degree in finance from Utah State University and an MBA from the University of Tulsa.

#### Q HOW HAS YOUR PAST EXPERIENCE PREPARED YOU FOR YOUR CURRENT POSITION?

Throughout my career, I have maintained a passion for customers and service excellence. Ensuring that customers' experiences are first-rate and provide value is critical to the success of all service organizations. An important part of my job is making certain that employees closest to customers have the knowledge and authority they need to ensure Baxter BioPharma Solutions customers have a positive experience.

#### Q WHAT CHALLENGES WILL CMOs FACE IN THE NEXT FEW YEARS?

One of the greatest challenges that CMOs will face is over-capacity in the market. In recent years, big Pharma and CMOs have expanded manufacturing capacity, and many CMOs are struggling to differentiate their offering. At the same time, CMOs must be prepared to respond to the growing biologic drug pipeline and increasing need for aseptic formulation, fill and finish operations.

#### Q WHAT IS BPS'S STRATEGY FOR SUCCESS?

When pharmaceutical companies partner with a CMO, they are buying more than a syringe or vial. They're seeking quality manufacturing expertise and processes, as well as an overall positive customer experience.

BPS is uniquely qualified to be a global manufacturing partner. To set ourselves apart from other CMOs, we focus on delivering

value to customers throughout their products' life-cycle: from formulation to launch, and through product differentiation via reformulation and enhanced packaging.

In addition, BPS maintains a strong service mentality throughout our organization. Our employees are empowered to treat customers' molecules as if their own health depends on it -- because, in reality, it may.

#### Q YOU MENTIONED SERVICE. WHAT CHANGES HAVE YOU MADE IN THE LAST SIX MONTHS TO PROVIDE POSITIVE SERVICE?

Over the past six months, BPS has spent significant time and energy evaluating customer feedback so that we truly understand customer needs and requirements. This information has helped us learn what we need to do internally to improve the experience that customers have as they do business with Baxter.

To enhance our processes, we have employed Lean Six Sigma tools, which help organizations balance improvements in quality and speed in order to improve overall service quality, as defined by customers. As a consequence, we, literally, have built an infrastructure around the customer experience.

I am excited about the progress that we have made toward providing a superior customer experience in each of our facilities.

#### Q CAN YOU ELABORATE ON RECENT CLIENT FEEDBACK?

Our facility in Halle, Germany -- where we work with highly sophisticated molecules -- has a history of providing customers

## NEWS BRIEFS



### LINE 8 LIQUID FILLING ONLINE AT BAXTER'S BIOPHARMA SOLUTIONS BLOOMINGTON FACILITY

The installation and validation of Line 8's liquid filling capabilities at Baxter's Bloomington, Indiana facility is complete and customers are committed to produce their drugs on the line beginning in Q4 of this year. Line 8's custom design has the potential to improve yield and reduce the risk of contamination, as well as providing the distinctive technologies needed to produce many of the new biologics and special small molecule formulations.

- **IMPROVED YIELD** – Line 8 is the first Bloomington vial line to utilize 100-percent, in-line fill volume analysis. This technology provides fill volume checks on 100 percent of the vials; this may enable yield improvements by eliminating destructive testing methods or by reducing the cost of a failure when random testing is used.
- **REDUCED RISK OF CONTAMINATION** – Line 8 applies the latest technology to increase control over the manufacturing process and reduce the risk of contamination. Line 8 uses a unique on-line vision system to measure stopper seating prior to crimping. This automated, 100-percent inspection can detect improperly seated stoppers that could increase the risk of contamination between the vial and seal in transit to the capping room.
- **UNIQUE CAPABILITIES FOR SENSITIVE MOLECULES** – Line 8 is one of the few contract manufacturing lines worldwide to incorporate technology that can provide advanced cold-chain management. Line 8, which keeps the tank chilled during filling, features technology designed to maintain the entire filling system and loading table at a controlled cold temperature.
- In addition to these unique capabilities, Line 8 includes an Insoluble Formulation Technology suite that enables commercial batches of products to be formulated.

Part of the Bloomington facility expansion, the innovative design and capabilities of Line 8 were key factors in Baxter being awarded the 2006 Pharmaceutical Facility of the Year by the International Society of Pharmaceutical Engineers.



### PHARMACEUTICAL LEADER AT BAXTER RETIRES AFTER 25 YEARS



Renowned pioneer in the pharmaceutical industry, Dr. Ted Roseman, Global Head of R&D, Baxter Pharmaceuticals & Technologies (BPT), is retiring from Baxter after 25 years of extraordinary leadership.

Ted's drive and dedication to Baxter and the improvement of the pharmaceutical industry is evident in his remarkable contributions to nearly every discipline at

Baxter including responsibilities for engineering, regulatory, clinical and R&D quality, in addition to his R&D organization.

(CONTINUES ON PAGE 4)

with a tremendous experience. As a consequence, customer satisfaction with this facility has been consistently high.

Because this facility, in my opinion, is the best in class in our industry, Baxter has leveraged some of that expertise into our other operations. Although we are in the initial phases of these changes, customer feedback has been very positive.

#### **Q** YOU'VE MADE A LOT OF CHANGES, SO HOW WILL YOU KNOW THAT YOU HAVE BEEN SUCCESSFUL?

Success will be measured in many different ways. Initially, direct customer feedback relative to quality, delivery and the overall experience will be a good indicator of whether these changes are having a significant impact.

Positive customer feedback, then, will translate into higher scores through Net Promoter, a discipline by which companies grow profitably by focusing on their customers.

To sustain these improvements, a "service culture" must be a part of our DNA at all levels of the BPS organization. Our goal is for customers to witness the BPS service culture every day in the way our employees make decisions regarding their business and their molecule.

#### **LOOKING FOR DYNAMIC SOLUTIONS TO POWER YOUR SUCCESS?**

Connect to the resources you need.



(CONTINUED FROM PAGE 3)

"I've had the opportunity to work with the best and brightest in the business," said Roseman. "It's what motivated me to come to Baxter and what kept me here. The breadth and depth of our capabilities is second to none in the pharma world."

As a leader, teammate and mentor, Ted has had a lasting impact on the pharmaceutical industry and he encourages new talent to consider the amazing opportunities available at Baxter. Ted has proven Baxter is an environment where leading scientists can enjoy a rewarding career.

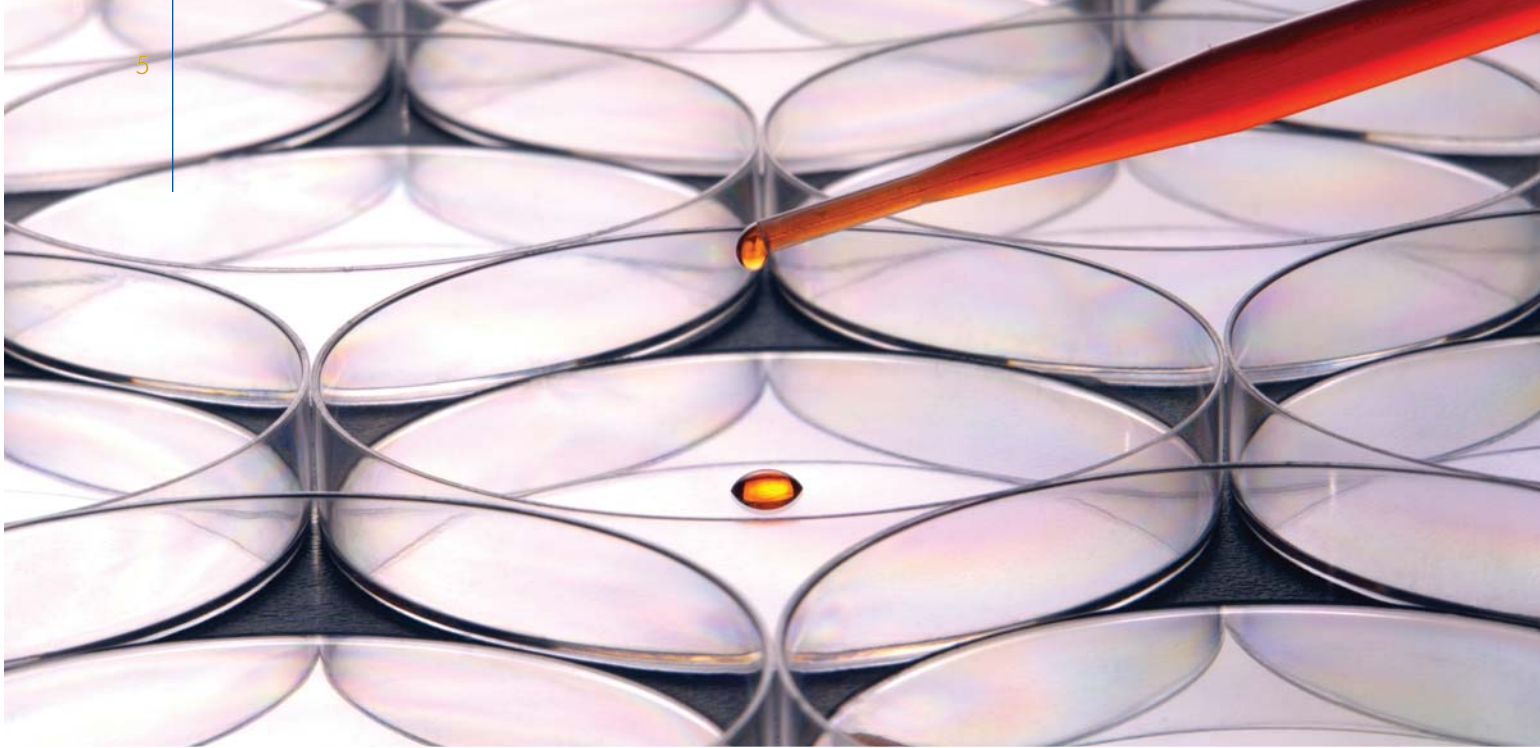
"I want all budding scientists to know that they can work on cutting-edge research at Baxter. Baxter is constantly evolving and has demonstrated a very strong commitment to R&D."

Baxter thanks Ted for his leadership and dedication. As Ted begins a new chapter in his life, his many accomplishments at Baxter will continue to be celebrated and honored.

#### RESEARCH AND DEVELOPMENT EXCELLENCE IN LYOPHILIZATION AT BAXTER BIOPHARMA IN BLOOMINGTON, IN

As an industry-leading resource, the Baxter Lyophilization Center of Excellence (BLCE) is supported by top-educators in the specialized field of freeze-dried products. The center consistently excels in developing new lyophilization procedures which optimize efficiency and yield including: proven strategic approach to cycle development vs. traditional trial-and-error techniques, targeted lab-to-product correlation for efficient manufacturing and cost control as well as various other areas of expertise. Below is a list of the BLCE's outstanding accomplishments and expertise:

- Combined 250 years of experience in development of parenteral products
- Expertise in overcoming protein aggregation stability problems
- Industry leading analytical methodologies for measuring protein aggregation
- Particular expertise in capillary electrophoresis including cIEF and cGE
- Developed or optimized lyophilization formulations and cycles for 40 clients
- 110 publications and presentations in past 5 years
- 120 client product, process and analytical method development projects
- Recipient of 2007 AAPS PT Section Research Achievement Award
- Chairman of USP Expert Committee on Industrial Parenteral Products
- Teachers of international parenteral and lyophilization courses
- Author of Parenterals chapter in *Remington's Pharmaceutical Sciences*
- Former College of Pharmacy professors, currently adjunct professors
- Editors and authors of *Development and Manufacture of Protein Pharmaceuticals*
- Author of book on *Parenteral Quality Control*, 3 editions



## UPCOMING PRESENTATIONS AND POSTERS BY BAXTER SCIENTISTS

PRESENTATION: *Financial Model for Converting from a Vial to a Pre-Filled Syringe*, OCT 6, 2008 M. Borlet, 2008 Parenteral Drug Association (PDA) Universe of Prefilled Syringes and Injection Devices San Diego

POSTER: *Computational Method of Treating Kinetic Data Acquired by Using a pH-stat*, NOV 16 – 20, 2008 J.E. Kipp, S. Benton and G. Desal AAPS Annual Meeting Atlanta

## RECENT PRESENTATIONS, POSTERS AND MANUSCRIPTS BY BAXTER SCIENTISTS

POSTER: *Can Mortality be Lowered by Switching from an Open to a Closed System?*, APR 5 – 8, 2008 V.D. Rosenthal, F. Franzelli, R. Salomao, M.S. Rangel-Frausto, F. Higuera and K. Barker, The Society for Healthcare Epidemiology of America (SHEA) 2008 Annual Meeting

PODIUM: *Product Development Considerations with Injectable Nanosuspensions: Case Studies*, MAY 12 – 14, 2008 J. Wong, University of Wisconsin-Madison

MANUSCRIPT: *Development and Qualifications of an HPLC Method for Anesthetic Compounds in Solutions Containing Hylenex*, MAY 2008 S. Karmarkar, S. Lee, F. Gallo, A. Tang and E. Moore, *Journal of Pharmaceutical and Biomedical Analysis*

POSTER: *Are BSI Risk Factors Modified When Using a Closed Infusion System?*, JUN 15 – 19, 2008 V.D. Rosenthal, F. Franzelli, R. Salomao, M.S. Rangel-Frausto, F. Higuera and K. Barker, Association for Professionals in Infection Control (APIC) 2008 Annual Meeting

PODIUM: *Freeze-Drying Cycle Optimization Facilitated by Mathematical Modeling and Tunable Diode Laser Absorption Spectroscopy (TDLAS)*, AUG 8, 2008 W. Kuu, Breckenridge Lyophilization Conference

MANUSCRIPT: *Physicochemical Stability of Phospholipid Dispersed Suspensions of Crystalline Itraconazole*, AUG 28, 2008 J. Werling, S. Graham, H. Owens, L. Nair, T. Gonyon and P.W. Carter, *European Journal of Pharmaceutics and Biopharmaceutics*

PRESENTATION: *Challenges and Opportunities in Monoclonal Antibody Delivery*, SEP 22 – 23, 2008 S. White, Drug Delivery Global Summit

PRESENTATION: *Lean Six Sigma in the Pharma Manufacturing Industry*, SEP 22 – 23, 2008 W. Botha, Global Pharma Manufacturing Summit

POSTER: *Quantitative Risk Modeling and Simulation of Parenteral Products Reduces Patient Infection Risks*, SEP 22 – 23, 2008 E. Tidswell, GTCbio's Bugs & Drugs Conference



### FOR MORE INFORMATION

about these presentations, posters and manuscripts: please contact Kim Fielder at [kim\\_fielder@baxter.com](mailto:kim_fielder@baxter.com).



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### About Baxter

Baxter's BioPharma Solutions business offers a comprehensive portfolio of products and services for the pharmaceutical and biotechnology markets. Baxter provides innovative formulation technologies, high-volume contract manufacturing and enhanced packaging to its customers, a full range of resources to support initial drug formulation through commercial scale-up as well as introduction and life-cycle management. As a parenteral drug development partner, Baxter offers the potential to improve drug safety and efficacy, increase product differentiation and market potential, and enhance patient compliance and end-user preference.

If you would like more information about Baxter's portfolio of products and services, please visit our Web site, [www.baxterbiopharmasolutions.com](http://www.baxterbiopharmasolutions.com), or contact:

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 AAPS ANNUAL MEETING & EXPOSITION  
 Baxter Exhibiting at Booth #1914

FRANKFURT, GERMANY  
 SEP 30 - OCT 2, 2008  
 ICSE 2008  
 Baxter Exhibiting at Booth #4148

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