



September 2007

## ~ WELCOME ~

As we approach the close of the third quarter, Fette is poised, once again, to achieve record sales for 2007. With constant product advancements, cutting edge technology, and our position as the leading innovator in the industry, Fette's future is brighter than ever. We look forward to raising the bar even higher with the products and services we have planned for 2008.

At Fette America, we are constantly enhancing our customer service and finding new ways to augment our clients' experiences with Fette machinery. One example is the introduction of the **Fette Pocket User Reference Guide**, a practical reference booklet for operators, designed to be especially helpful for new users. (See related story.) Please contact us for your complimentary copy.

We are also proud to announce the addition of our third, full-time service technician dedicated to servicing our clients in Puerto Rico. With a staff of 15 full-time service technicians in the U.S. and Canada alone, Fette offers the most knowledgeable and specialized technical support staff in the industry. The size and diversity of our technical staff enables us to offer something unprecedented in our field — on-site, emergency service within 24 hours.

In the end, our most important assets are our customers, and we will continue to make your satisfaction with Fette products and service our first priority. It is not only our duty to you, but our way of demonstrating our appreciation for your support. As always, we welcome your comments and suggestions, as they will help us to improve our ability to serve you even better in the future.

Best Regards,  
Sean Scully, Vice President of Operations

## Advances in Double-Layer Technology

For many years, Fette has produced top-notch double-layer tablet presses that are well ahead of the technological curve in this manufacturing niche. While still not as popular as mono-layer tablets, it appears that double-layer or "bi-layer" tablets are becoming a more attractive dosage option for pharmaceutical manufacturers.

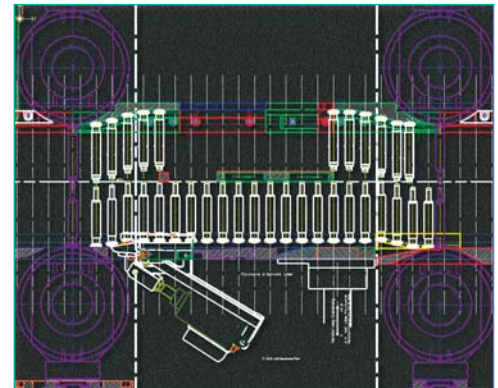
Marketing groups are sometimes interested in the use of a double-layer tablet because of its obvious visual appeal, especially in the case of uncoated tablets that utilize different color granulations for the different layers. The double-layer dosage form can also prove to be efficacious when the different layers are comprised of products with varying degrees of bio-availability. More recently, some manufacturers are finding that developing a double-layer version of a historical or "legacy" product may allow them to enjoy a longer product life-cycle, as patent protection begins to wane.

There are certain key areas of double-layer compression that manufacturers of solid dosage forms would be concerned about. While high output is usually of primary importance, there are many other features that are critical to the effectiveness of a modern double-layer press. They include:

- The ability to rapidly produce tablets of the desired weight, thickness and hardness, while maintaining crisp, clear lines of demarcation between layers
- The ability to rapidly produce first layer samples and automatically remove them from the press
- An efficient dust extraction system for preventing cross-contamination of layers, and for maintaining high yields, which are generally lower with

double-layer than they are for mono-layer products

- Weight control and adjustment systems that allow independent control of the different layers
- The ability to quickly convert the tablet press from a double-layer orientation back to a mono-layer orientation



Given the increasing popularity of double-layer products it should come as no surprise that Fette GmbH will continue to develop and optimize their technologies for handling this dosage form. Some of these new features will revolutionize the efficiency with which double-layer products can be manufactured. Here's a list of some of the more important new ideas that have either already been developed by Fette GmbH or are in the process of being researched:

- A feature that will allow the lower punch tips to be raised to the top of the die cavity during a first-layer sampling interval, thereby ensuring that no partial tablets can be formed at that time. This will virtually eliminate concerns that a "double-layer only" tablet can accidentally make its way to the "good" side of the discharge chute.

*continued on next page*

## Advances in Double-Layer Technology *(continued from front cover)*

- A pneumatically-actuated main compression station on the first-layer side of the press will allow an almost immediate increase in compression force on that layer during a sampling interval, so that the sample will be robust enough to handle and weigh. The station will adjust so rapidly that this temporary increase in compression force can be made in less than one second!
- A pneumatically-actuated sampling cam for ejecting the first-layer samples out of the die cavity. While this feature has been an integral part of Fette's double-layer technology for some time, recent advances have made it even faster than before. It, too, can adjust to the desired position in less than one second!
- A new point-specific vacuum pick-up, positioned just after the second-layer Fill-o-matic, that will utilize a small blast of air to clear the tooling surfaces of any residual product, and simultaneously utilize a powerful vacuum to remove any product from the die area before the dies pass under the second-layer compression rolls.
- Higher resolution load cells can be made available for the first-layer compression, allowing for accurate measurement of the small side one forces required for

optimal cohesion between layers. These load cells will allow for measurement of forces as small as 100-200 newtons.

Fette America's staff of service engineers boasts more direct experience with producing double-layer tablets than any other tablet press vendor in the pharmaceutical industry. Please contact us for more information on the availability of any of the aforementioned options, or to discuss a trial in our Rockaway, New Jersey laboratories.

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## Everyday Key Contacts at Fette America

Time is a more precious commodity than ever before. Cell phones, e-mail and BlackBerries have raised the bar in terms of a company's ability to be responsive, but they've also created higher than ever expectations for that same responsiveness. Despite all of these communication technologies, one can sometimes encounter almost paradoxical difficulty in contacting those with whom they need to speak. Everybody seems to be in a meeting these days, and a company's clients should not suffer as a result.

Fette America has a clear understanding of how important it is for our clients to be able to quickly reach an individual who can assist them. Our clients rely not only on our equipment's performance but also on our ability to help them keep that equipment performing at an optimal level. During normal business hours (we also offer after-hours emergency telephone service — please see the April 2007 issue of our newsletter) there are a number of key individuals based in Rockaway who act as invaluable everyday contacts. All can be reached through Fette America's main number at 973-586-8722. They are:



- **Cathi Mendel, Manager of Spare Parts** – Cathi has been with Fette America for 10 years now and has been the Manager of the Parts Group for 4 years. Her knowledge of our spare parts business, as well as our customer base, is unrivaled. She can quickly help a client identify an appropriate part, check availability and complete the ordering process. She has detailed knowledge of how Fette Germany's spare parts department works and is therefore often able to expedite things for our customers. She also has four full-time spare parts personnel to back her up, should she be unavailable: Bill Bamford, John Lucibello, Dave Woodson and Chris Lucibello.
- **Debbie Leech, Sales Coordinator** – Debbie (one of two Debbies on Fette America's staff) has been a Fette America employee for 5 years. She plays an important role in the day-to-day sales operation, often serving as the conduit through which our new equipment proposals are routed to our customers. She also facilitates delivery-related issues for our clients by keeping on top of Fette Germany's shipment schedules, updating our clients with respect to delivery dates and coordinating logistical details with various transportation companies.
- **Debbie Harrigan, Manager, Service Administration** – Debbie is another long-time employee, having been with Fette America for 8 years now. She spends a great deal of her time making certain we accommodate requests for service and installation work as quickly as possible. Our service calendar is very dynamic and can change numerous times during the day, but Debbie always knows where the service staff members are, so she can put our clients in touch with them whenever they need immediate assistance.
- **Courtney Valdeon, Manager, Sales & Operations Administration** – Courtney is into her 8th year with Fette America. She plays an important role in the day-to-day operations by dealing with a variety of responsibilities, such as overseeing the completion of user requirement specifications, coordinating important project dialogue between different groups, and directing clients to the most appropriate individual for rapid resolution of issues. If someone isn't sure who a client should be speaking with, Courtney will know who to direct them to.

# Webnotes

Fette America's website is in the process of receiving a facelift. We're excited about the new changes, which promise to make the site more navigable, informative and useful. We envision making the site not only a repository for dynamic information, but also an interactive medium through which visitors can request machines, spare parts, and service quotes, make direct contact with key personnel, and stay on top of Fette America's plans for select shows and exhibits.

Users will navigate the site from the following primary links:

- **Tablet Presses & Ancillary Equipment** – Detailed information on specifications, capacities, dimensions and utility requirements for all of Fette's presses and related equipment.
- **Parts** – Descriptions of current inventory, access to recommended spare parts lists for specific equipment models, and links to our "Request a Quote" page.
- **After Sales & Support** – Important information about our technical services group, including our 24/7 emergency technical service phone number.
- **Absolut Dust Collection** – Information and specifications about Fette-Absolut's line of high-containment filtration and dust collection units.
- **Training & Documentation** – Valuable links to compression theory outlines, control system descriptions, and preventative maintenance procedures. Detailed information on our level-based training program and the new VRTrain interactive training software.
- **News & Events** – Fette America's schedule for upcoming trade shows and training seminars, including dates, venues and locations.
- **Contact Us** – A key personnel list, as shown below, will allow users to quickly determine who they need to contact for any particular issue.

**Vice President Sales & Operations:** Richard Derickson  
[rderickson@fetteamerica.com](mailto:rderickson@fetteamerica.com)

**Vice President of Operations:** Sean Scully  
[sscully@fetteamerica.com](mailto:sscully@fetteamerica.com)

**Vice President of Sales:** Laura Frain  
[lfrain@ptd.net](mailto:lfrain@ptd.net)

**Manager, Spare Parts:** Cathi Mendel  
[cmendel@fetteamerica.com](mailto:cmendel@fetteamerica.com)



**Lab Manager:** Ty Bullock  
[tbullock@fetteamerica.com](mailto:tbullock@fetteamerica.com)

**Technical Products Manager (Fette Absolut, Reconditioned Equipment & Tooling):** James Mossop  
[jmossop@fetteamerica.com](mailto:jmossop@fetteamerica.com)

**Special Projects Manager (WiP & Room Design):** Erik Barman  
[ebarman@fetteamerica.com](mailto:ebarman@fetteamerica.com)

**Training & Documentation:** Bill Garneau  
[bgarneau@fetteamerica.com](mailto:bgarneau@fetteamerica.com)

**Service Manager:** Keith Lindemann  
[klindemann@fetteamerica.com](mailto:klindemann@fetteamerica.com)

**Manager, Service Administration (Technician Scheduling & Service Quotes):** Deborah Harrigan  
[dharrigan@fetteamerica.com](mailto:dharrigan@fetteamerica.com)

**Controller (Accounts Payable & Accounts Receivable):** Philip Meyers  
[pmeyers@fetteamerica.com](mailto:pmeyers@fetteamerica.com)

**Manager, Sales & Operations Administration (Sales Support & Information Requests):** Courtney Valdeon  
[cvaldeon@fetteamerica.com](mailto:cvaldeon@fetteamerica.com)

The revamped site will serve as one of the most convenient ways to stay on top of Fette's newest technological advances. A few mouse clicks will put the most up-to-date equipment specifications at one's fingertips. Site visitors can sign up for our mailing list, so that they may receive special monthly spare parts offers, training seminar notifications and future issues of this newsletter. The new website should be up and functional by mid-August 2007.

# Latest Technological Developments and New Software Features

Fette GmbH is a dynamic company, with a strong research and development team that strives to continually develop equipment and features that enhance and simplify the use of Fette's technology in the field. Number one status allows no respite from the need to always stay a step ahead of the competition. Our newsletter serves as a launching pad for announcing the release of Fette's more notable new developments. Here are some of those that have been recently made available or that will soon be available.

## Technological Developments:

- Option "871" for double-layer manufacturing will include key features that take double-layer manufacturing to another level. Please refer to the section entitled "Advances in Double-Layer Technology" for more details.
- An adjustable fill cam that will allow Fette tablet press users the flexibility of using only one cam for a much wider range of filling depths than ever before. The cam



will essentially act as 6mm, 8mm, 10mm and 12mm cams, all rolled into one. Settings are electronically monitored. Adjustable fill cams are available for i-series presses.

- An improved multi-layer feeding mechanism for the 102i research and development press. Manufactured from high-impact acrylic, the feed mechanism will allow for unencumbered visual inspection of the product level in each hopper, with a significant reduction in component weight.
- A dust-tight discharge chute that reduces operator exposure levels, lowers noise emissions, and improves overall cleanliness. Available for new Fette presses, this option will be designed so that it can also be retro-fitted for our PT and P generations of machines.
- An enhanced wash program on Fette's Wash-in-Place presses will now allow the

user the option of utilizing two separate waste water discharge valves. One valve can be used for discharging water with a high concentration of active product and the other can be used for water with minimally active concentrations.

## Software features made available in Visual Version 6.27:

- A new hot key is available that will allow users to easily and directly access the CheckMaster screen.
- Users of either the 1200i or 102i presses will now be able to measure dwell time when utilizing the single tablet compression feature.
- Users will be prompted by a pop-up window if an attempt is made to start a press when no active batch has been selected.
- Option 745 will allow users of OCIF to capture recipe names and version numbers.
- Production data for samples is now written into a .csv file.
- Ethernet communication with the Absolut Cephir dust collection unit can now be established.
- A backup disk for all batch data can be created from the backup disk menu utility.

## Runaway VRTrain Picks Up Speed —Success in Puerto Rico

As referenced in our April newsletter (see "VRTrain Keeps Rolling"), VRTrain, the interactive training software that is the result of a collaborative effort between Fette America and Product Animations, is starting to pay big dividends for users in the field. The fully-immersive, virtual 3-D environment software is garnering rave reviews from those who have utilized it in their own training programs. Most recently we spoke with personnel at McNeil Consumer Healthcare in Las Piedras, Puerto Rico, about their own experiences with VRTrain. McNeil began utilizing the program in April of 2007, and the following points summarize their experiences to date.

- Operators new to compression begin their orientation to the new department on VRTrain, rather than using a real tablet press.



- Average training times, per operator, for major cleaning on a tablet press have been reduced by one full week!
- VRTrain serves as an integral visual aid that facilitates orientation for the operator once on-the-job training commences.
- The software acts as a source of unlimited refresher material once an operator

has started to develop real skills. An actual press need not be available for ongoing training, so an operator's skill level can continue to grow even if a company's real presses are currently being utilized for production requirements.

VRTrain utilizes a progressive training approach for becoming acquainted with key machine parts and activities. The user progresses from reference to practice modes and then completes their training with a test mode. Training with VRTrain, especially for new operators, provides an environment in which one can develop greater confidence levels that will then lead to more comprehensive learning. Please contact us at 973-586-8722 or visit our newly revised website at [www.fetteamerica.com](http://www.fetteamerica.com) for information.

# Quick Reference Pocket Guide Now Available

Fette America is proud to offer this free pocket-sized guide to help our customers diagnose and manage a wide range of operational and service issues. The 20 page booklet includes photos, diagrams, and operation instructions, as well as troubleshooting instructions covering everything from tablet weight variation to picking and sticking. For your free copy call (973) 586-8722.



## EMPLOYEE SPOTLIGHT

### *Sean Scully, Vice President of Operations*

Sean is one of the three founding members of Fette America, starting at the company's inception in 1991. Working with Rich Derickson, Sean's responsibilities included designing the layout of the building, procurement of office and warehouse equipment, and creating the spare parts department, as well as setting up the in-house sales and service departments. Fortunately for Fette America, Sean's background provided the experience and attention to detail that these tasks required.

A volunteer firefighter from 1976 until 1984, Sean's first job was at the Rockland County Fire Training Center, where he prepared equipment for the training of all the County's volunteer firefighters and full-time police officers. He also prepared the helicopters for search and rescue missions.

Sean then went to work for Barr Laboratories where he started as a tablet press operator. After a year and a half, he was promoted to Compression Supervisor,



but trained in all manufacturing departments: Packaging, Blending, Granulation, Encapsulation, and Coating. Soon he was promoted to Manager of Compression and was responsible for daily operations 24/7, meeting with FDA inspectors, purchasing approval, new product development, and departmental SOPs, as well as personnel and union negotiations.

In 1991 Sean came to work for Fette America as In-House Sales & Service and was soon promoted to Manager of Spare

Parts and Technical Services. However, his involvement in everything from service to sales prompted his promotion to Director of Operations where all departments, except Sales and Finance, report directly to him. Sean is involved with sales, service, advertising, the lab, and overseeing Fette America's day-to-day operations. In April of this year, Sean was promoted to Vice President of Operations and continues to work closely with Rich Derickson and Laura Frain.

A man of many talents, Sean currently serves as one of nine members of the Tablet Specification Steering Committee. This Committee meets in Washington, DC every three years and issues the TSM manual that details the tooling specifications for the United States and Canada. He holds a patent on a tooling storage box and once received the Fire Chiefs' Association Award.

Sean has been married for twenty-three years to his wife, Jeannie and has two children; a twenty-two year old son and a nineteen year old daughter. He enjoys caring for his ponds and raising koi.

# Upcoming Events



| Scheduled Date         | Type of Training /Show | Where                 |
|------------------------|------------------------|-----------------------|
| September 25           | Managers Seminar       | Fette America         |
| October 23 – 24        | Training Seminar       | Midwest               |
| November 11 – 15       | AAPS                   | San Diego, CA         |
| December 4 – 5         | Training Seminar       | Puerto Rico           |
| February 14 – 15, 2008 | Interphex PR           | San Juan, Puerto Rico |
| March 26 – 28, 2008    | Interphex              | Philadelphia, PA      |
| April 24 – 30, 2008    | Interpack              | Düsseldorf, Germany   |
| May 6 – 8, 2008        | Powder & Bulk          | Chicago, IL           |

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## ~ In This Issue ~

-  • New Double-Layer Technology
-  • Latest Software Features
-  • Virtual 3D Training Update
-  • New Website
-  • Free pocket Guide