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## The Coaches Box

By Ric Zakour, General Manager and Sr. Vice President, BioServices

Well, it has been a year since our last issue, and a lot has happened. During that time, we "survived" another winter, have had a good spring and summer, and to date, we have not had any hurricanes. We did help our sister company, McKesson Specialty New Orleans to keep functioning recently during Hurricane Ivan. BioServices closed another successful fiscal year in March, and we accomplished many but NOT ALL of our business Score Card goals for FY04. We started FY05 in April with bigger and better goals, but we have encountered some bumps along the road in all aspects of our business. For the first half of this fiscal year, we are behind in almost every Score Card measure that can be determined. This is not good! I hope that we are not being lulled into a false sense of security because we have overcome similar challenges in the past. We need to keep our eye on the prize and keep focused, not just for the sake of growing, but because we want to become a better organization. To this end, I am very disappointed in our quality performance measures. Year to date, we have almost as many major quality non-conformances as we had all of last year. If we ship the wrong product or place the wrong information onto a label for a drug undergoing clinical evaluations this could affect people's lives. We need to think about where our products are going, and what we are doing, that makes a difference because the people we serve are counting on us to do it right.

Our financial performance has also been lacking this year. BSD is the only part of the company operating ahead of plan, and my congratulations go out to them. Keep up the good work. Both the Government and PSD sections of the company are lagging behind plan. You might suggest that the financial targets were set too high. I think not. The budget was put together as a

collaborative effort based on input received from the people who manage the respective business areas on a day to day basis. Will we be able to make up the short fall? I do not know, but we must try to do it. Although a portion of achieving our financial goal is out of our control, i.e., the timing of some of the Government expenditures, there are a number of things that we all can do to help correct this situation. For one, we all need to be salespeople. Look for opportunities in any way you can to bring new business to the company. It may not benefit us today, but who knows what it can lead to in the future. Secondly, we must focus on customer service. Maybe I am being overly sensitive, but I seem to be receiving an increasing number of negative feedback comments lately from our customers across all lines of business. I find this very disappointing. We must be responsive to all of our customers when they contact us, and we should endeavor to help them to fulfill their commitments. Remember the "C" in ICARE stands for Customer-centered. Last, and most importantly, we must focus on quality. A couple of the non-conformances cited above have been very costly this year. These process failures have had direct negative "bottom line" effects on our profits, as well as causing our customers to be reluctant about giving us future business. This can lead to a

negative spiral where the failure to meet customer requirements and expectations results in the reduction or loss of business. We must all be committed to reversing this trend.

BioServices' personnel have always prided themselves in providing high quality, timely and accurate services and being responsive to customer needs and expectations.

There is a historic "Can Do" attitude that has existed since our inception. Although we are not the little company that we once were, I believe that we can rekindle that spirit and channel it into ways that will allow us to achieve great things. I would like for each and every one of us to make a commitment to look deep within ourselves to find ways that we can do it better. This is a critical time for BioServices, and I know that we have it in us to accomplish anything that we set out to do. I am proud to be leading you in this effort and I know that we will succeed.

There are several recent (FY05) accomplishments that I would like to recognize:

On September 28, we won the recompetition of the NCI-DCP contract. The base level contract is for \$19.2 million for 5 years, and if all options are exercised, it is potentially worth \$30 million over 7 years. Congratulations to Susan Muhr and her team that were involved in this effort.

In August, we signed an agreement forming a strategic alliance with InforMedix. InforMedix is a local company, and we will jointly provide a turnkey patient-compliance and medication-dispensing solution for use in clinical trials. Anita Dopkosky and her staff led the effort in making this happen.

In June, we hosted a reception at the McKesson Vision Center in San Francisco during the BIO 2004 Annual Meeting. This was a very successful event attended by both clients and McKesson corporate representatives. Pat Hindes did a great job in coordinating all of the complicated logistics for this event.

In May, the new BioServices facility in Germantown became operational, and three contracts relocated to this site. These included the NIH AIDS Reagent Repository and the NCCAM Cranberry contract. More recently, the NIAID CRPMC has also occupied some of the space in this facility while keeping their main operations at the First Street location. This will also become the new home for the NCI-DCP contract. Chuck Gambrell led the facilities effort to accomplish this along with all of the project teams involved in making the move.

In April, we received a 94% rating toward our Award Fee on the NCI-SAIC Frederick contract. Kathleen Groover and all of her staff are to be commended for this accomplishment.

*On behalf of McKesson BioServices' Communication Committee, this issue has been dedicated to the memory of Camille Theresa Moore, who is deeply missed by her co-workers. Jim eloquently describes her dedication on Page 2. A special thank you to show our appreciation to our dedicated employees who continue to write regular feature articles, and welcome all the new participants in this issue for their contribution and expanding our knowledge about the various departments within BioServices. We encourage everyone to get involved. This is your newsletter. Thank you!*

*Pat Hindes, Managing Editor  
Jim D'Amato, Kim Wesmiller,  
and Cheryl Sollars*



In Memoriam  
*Camille Theresa Moore*  
*October 15, 1970-July 1, 2004*

by Jim D'Amato

Camille Theresa Moore was born on October 15, 1970 in Brooklyn, New York, and subsequently moved to Maryland with her parents. She graduated from J. F. Kennedy High School in 1989, then continued her higher education and graduated from Morgan State University with a BS in 1995. Last November 2003, Camille Moore joined McKesson BioServices as a staff microbiologist working in our PSD Analytical Laboratory.

She worked very closely with me and Susan Muhr to develop the Microbiology Laboratory and achieve operational status. It was a pleasure to work with her because she not only possessed valuable technical skills, but she demonstrated remarkable adaptability and initiative that was crucial to achieving operational status in a timely and cost effective manner. Camille brought to her new job many valuable technical skills and a true zest for life. She was an avid traveler visiting many cities within the US and Europe. She also was an adventurer at heart, and enjoyed hiking, rafting, and she fulfilled her ultimate dream by learning how to fly a single engine aircraft.

Camille could be counted on to get the job done on or before expected, and all work reflected her full and qualified commitment to Quality Assurance. Her many personal gifts enabled her to become not only a highly effective employee, but she was also a great co-worker. Her positive attitude, professionalism and deep concern for her fellow staff members and customers won the praise and respect of her supervisors, fellow workers, and those that relied on her services. Her hard work, unqualified commitment to quality and McKesson BioServices brought great credit upon herself, as well as our Company.

Camille unexpectedly passed away at her family home on July 1, 2004 surrounded by the people she loved and a family that adored her. All who knew her will dearly miss her, but she left us this thought to remember her by:

*LOVE bears all things,  
BELIEVES all things, and  
ENDURES all things.  
-- (1 Corinthians 13:7)*

## Bar Code Label Requirement

By Joe Buccine R.Ph. and Binh Hoang, Pharm.D.  
Clinical Research Products Management Center (CRPMC)

On February 25, 2004, the FDA released a final rule to require bar codes on the labels of all human prescription drug products, biological products, and Over-The-Counter (OTC) drug products that are commonly used in hospitals and dispensed pursuant to an order ([www.fda.gov/cber/barcodelabel.pdf](http://www.fda.gov/cber/barcodelabel.pdf)). The bar code must contain the National Drug Code (NDC) number in a linear bar code that meets EAN/UCC (European Article Council) standards. The NDC has three (3) parts, identifying the labeler/vendor, product, and package size. The product code is the second part of the NDC which corresponds to a drug, and identifies a specific strength, dosage form, and formulation for a particular firm.

The bar code rule, which FDA first proposed in March 2003, is designed to improve patient safety. The rule will help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify the right drug (in the right dose and right route of administration) is being given to the right patient at the right time. The rule also requires the use of machine-readable information on blood and blood component container labels to help reduce medication errors.

Bar coding can be expected to reduce the incidence of the following types of medication errors:

- Administering the wrong drug to a patient who is known to be allergic
- Administering the wrong drug to a patient or administering a drug to the wrong patient
- Administering the drug incorrectly
- Administering the drug at the wrong time
- Missing or duplicating doses.

According to a recent study, the number of variable pharmaceutical products has increased by 500 percent in ten (10) years and now totals over 17,000 separate trade and generic names. Therefore, we expect the annual costs of maintaining a system of unique NDC numbers by FDA to be \$2.4 million.

In contrast, bar code use could reduce hospital payments due to punitive damage awards from potential lawsuits. Moreover, current bar code systems are expected to avoid about 17 adverse drug events per year in an average hospital.

As a result, the FDA has examined the regulation and found that the expected benefits outweigh the cost and that the regulation would improve public health.

The Department of Veterans Affairs hospitals use bar code technology. It reports that medication-error rates are "practically zero," thanks in part to widespread implementation of bar coding, said Tom McGinnis, FDA's director of pharmacy affairs. He estimates that using bar codes will reduce medication errors by 50% over the next 20 years (ASHP News, February 25, 2004)

Drug products that received approval before February 25, 2004 must comply with the bar code requirement within two years. Drug products approved after February 25, 2004 must comply within 60 days. Investigational new drugs are exempt from this requirement. This exemption is referenced in 21 CFR Parts 201, 606, and 610: Bar Code Label Requirement for Human Drugs Products and Biological Products; Final Rule, section II.B.4.a comment 14. This exemption was addressed in response to a letter submitted by the CRPMC inquiring if investigational products would be subject to bar code requirements. FDA declined to require bar codes on investigational new drugs for two reasons:

1. The number of investigational new drugs is constantly changing, and that constant change would exhaust the number of available NDC numbers quickly.
2. Bar codes on investigational new drugs could result in misleading information or compromise the clinical study.

McKesson Corporation applauds FDA's final ruling and

predicts that demand for bar coding and other patient safety technology will greatly accelerate over the next five years, with point-of-care bar-code scanning becoming a generally accepted standard of care for the nation's hospitals. As a leader of bar-code

automation, McKesson is already delivering patient safety solutions to more than 10,000 hospitals, clinics and retail pharmacies. Further more, McKesson solutions are used to process more than 135 million bar-code medications every year. For more information, go to [www.mckesson.com/mcksafe](http://www.mckesson.com/mcksafe).

## South African Pharmacists Visit the Clinical Research Products Management Center

by John Ferinde, R.Ph., Principal Investigator  
Clinical Research Products Management Center (CRPMC)



Picture from left to right are John Ferinde, Tanuja Gengiah, and Andrew Gray.

Andrew and Tanuja are pharmacists from the Center for the AIDS Programme of Research in South Africa, which is located at Nelson R. Mandela School of Medicine, University of Natal, Durban, South Africa. This Adult AIDS Trial Group clinical site will be participating in AACTG protocol A5142. This protocol is a Phase III comparison of Lopinavir/ritonavir plus Efavirenz versus Lopinavir/ritonavir plus 2 NRTIs versus Efavirenz plus 2 NRTIs as initial therapy for HIV-1 infection. This protocol will provide therapy for 660 patients in the US and SA for two years.

Tanuja and Andy visited with John Ferinde, RPh, Principal Investigator and Tayech Tesfaye, PharmD on January 23, 2004 to discuss pharmaceutical supply logistics for this protocol. The first two shipments of antiretroviral drugs were valued at \$196,751. This high value shipment presented a challenge because it required an exemption from the South African Value Added Tax. Thanks to staff research, prior to shipment and good communication these shipments passed a full SA-customs inspection with no problems or taxation. John Ferinde's staff has started working on the second shipment, which will be valued over \$600,000.

# Management *Intuition: A Critical Leadership Skill*

By Jim D'Amato, Ph.D., HCLD, QA(RAB)  
QA Coordinator, Senior Scientist

*According to Dr. Weston H. Agor, of the Intelligence Company (Cocoa Beach, Florida), who has written books on intuition, modern corporations are now testing their top executives for not only how much intuitive ability they possess, but how much they use this invaluable, but elusive, mind power.*

## *What is Intuition?*

You can match the number of definitions to the number of people you ask, but as it can be boiled down to knowing for sure without knowing for certain. Others will say it's the same as a hunch, a gut feeling, an instinct or an inner knowing. Warren Bennis, a well-known author and leader in several fields, calls intuition his "inner voice."

He believes that listening to it and trusting it is one of the most important lessons of leadership that he has learned. Perhaps Dr. Jonas Salk offered the most appropriate definition when he said,

**"The intuitive mind tells the logical mind where to look next."**

Louis Pasteur probably struck another nerve when he said, **"Chance favors the prepared mind."**

Many researchers have discovered that intuitive hints might have proved baffling if they hadn't already filled their bright heads with meaningful information.

## *When is Intuition Needed?*

- When there is insufficient data, or not enough time to gather the data
- When there is too much information, or the data conflicts
- When data supports several options equally
- When decisions have to be made on the spur of the moment without time for data-gathering
- When a group's vision has grown cloudy and/or its mission seems inappropriate or obsolete

- Determining new inspiring visions and the overall direction of a group or organization
- Recognizing and employing the abilities of all individuals in that group or organization to achieve the highest effectiveness.

## *Sleeping on it.*

While some may consider intuition to be purely a paranormal function, many feel that it combines the elements of logic, experience, memory and the paranormal. The subconscious mind is constantly stirring those various components together. When they form some kind of conclusion, the subconscious may suddenly present that conclusion to the conscious mind and it is our task to keep our mind receptive to receive these important inspirations. Like any ability or skill, intuitive abilities can be sharpened and made more reliable by consistent and aware practice.

Research has shown intuition resides more in the right brain than in the left. It is also more a function of the subconscious than the conscious mind, and functions best when one is in a relaxed state. Therefore, the ideal time for such a purposeful approach is bedtime. We have two natural Alpha brainwave frequency times.

- When we're drifting off to sleep
- When we're waking

These are called our hypogogic and hypopompic periods, and they are both relaxed but aware. So we can lie down, get calm, and at the natural-Alpha-just-before-entering-sleep time explain to our subconscious mind what we already know about a situation, what help we need and when we need it. In short, we can make a specific assignment to the subconscious and go on blissfully to sleep.

When the conscious mind has bowed out, the subconscious is free to explore all its rich sources. It can use the sleep period to tape into the minds of people who don't close it out; to check on memory and experience; to investigate its paranormal sources which the conscious mind can't reach; to confer with an overarching intelligence. This is the mind's vast intuitive capability. Then when we have reached over hypopompic "coming-out-of-sleep" times, the subconscious can present to the awakening conscious mind its all-night findings. We have the testimony of many great thinkers, researchers and inventors to confirm this approach to intuitive help.

Now that the horse-and-buggy days have long been replaced by the global gallop, there's a greater need for intuitive knowing in all phases of living. Its contribution to personal guidance as well as to business acumen cannot be denied. But in the realm of leadership, intuitive wisdom is now a sine qua non. Many bright minds in our professional literature agree. So let's acknowledge intuition, and rely on it when logic and analysis aren't sufficient. Try it; you will be surprised at the results.

# The Rising of HIV Infection in Women: *Facts & Consequences*

By Neeraja Putta, R.Ph.  
Clinical Research Products Management Center

For more than twenty years, the numbers of HIV infected women has grown exponentially, so that now, virtually half of the infections in the world are amongst women. In Africa, the infection rate for women stands at 58%, rising to 67% in girls between the ages of 15 and 22. This is a cataclysm, plain and simple. As Table 1 demonstrates, we are depopulating parts of this world of its women.

Studies have shown that women are three times more likely to be infected with the AIDS virus through sexual intercourse than men because the vaginal wall is prone to sores and abrasion. Fear of violence prevents women from accessing HIV/AIDS information, being tested, disclosing their HIV status, accessing services for the prevention of HIV transmission to infants, and receiving treatment and counseling, even when they know they have been infected.

Age	Girls/Women	Boys/ Men
15 to 19	15.4%	1.2%
20 to 24	29.7%	8.4%
25 to 29	54.1%	29.7%

Table 1

The Clinical Research Products Management Center (CRPMC), operated by McKesson BioServices, is under contract to the National Institute of Health, National Institute of Allergy and Infectious Diseases, Division of AIDS. CRPMC is the storage and distribution center for the HIV investigational drugs and vaccines for many government sponsored clinical research trials worldwide.

CRPMC is participating in a mega study of 3,220 women, which will test PRO 2000/5 Gel and Buffer Gel versus a placebo to assess the effectiveness of these vaginal microbides for the prevention of HIV infection in women. It is important to recognize that women suffer from the same complications of AIDS that effect men, but they also suffer gender-specific manifestations such as recurrent vaginal infections and severe pelvic inflammatory diseases.

This microbicidal study involves many countries including Malawi, South Africa, Tanzania, Zimbabwe, Zambia and India. Theoretically, women whose HIV infections are detected early and receive appropriate treatment should survive as long as infected men. But, HIV infected women have less access to health care resources, lack social support, endure domestic violence and often are homeless. It is hoped that these studies will help bring an end to this nightmare that has plagued Africa as well as the rest of the world.

Sources:

1. <http://www.microbicides2004.org.UK>
2. [www.niaid.nih.gov/factsheets/women/hiv.com](http://www.niaid.nih.gov/factsheets/women/hiv.com)
3. [www.unaids.org](http://www.unaids.org)

## Employee Occupational Safety and Health Survey 2003-2004

By Dawn Eltermann, BSN, Director of OS&H

A survey was developed to obtain a better understanding of the safety needs of BioServices employees. Some questions asked included “How can you make your site safer?”, “Do you feel safe at work?”, and “What safety-training do you want for better performance at work?” The survey was sent to all employees and 53 responses were received from December 2003 to January 31, 2004. The goal of a 10% response rate was met and exceeded. The survey identified areas that the Occupational Safety and Health Division (OS&H) could focus on and/or investigate. Selected survey results and current plans of action are:

#	Selected Survey Recommendations	Plan of Action Underway
1	Requests for improved lighting at several facilities	Chuck Gambrell, Director of Facilities, is evaluating the need for additional lighting at various sites.
2	Repaving BSD 685 Parking Lot as a result of ice buildup	Chuck Gambrell, Director of Facilities, is working with the site landlord, and developing a re-paving plan before winter 2004 (proposed start date 11/10/04)
3	Employees considered the office a “safe” environment	OS&H provided Office and Electrical Safety training in 2004 to increase safety awareness in the office.
4	Review training for improved forklift equipment operation procedures	OS&H discussed the perception of unsafe forklift operation with managers. Managers subsequently held staff meetings regarding forklift safety and the proper operation of forklifts and related equipment.
5	Practical job application training, specifically, back safety and lifting.	OS&H reviewed videos and materials, and selected a new video that focuses on back safety as it relates to warehouse and material handling operation.
6	Conduct on site training for contacts/sites with large employee groups, resulting in reduced employee travel time and resulting in a larger audience being reached.	OS&H will provide on site training to operations requesting such services.

Note: OS&H found this survey was an extremely useful tool and assisted OS&H focus our efforts and resources in areas to better meet BioServices employees’ safety needs.

# DEFENDING THE T-CELL: A SUMMARY OF ANTIRETROVIRAL DRUG THERAPY

by Joe Buccine, R.Ph.  
Clinical Research Products Management Center (CRPMC)

February 2004 - Once prevention fails and HIV invades the human body, the immunologic system launches mortal combat. The virus is an unbeatable foe. It is a T-cell killing machine. HIV lives on and on, dying only when its host deceases. No pharmacologic bullets can kill it. The best therapy only slows it down.

HIV's prime target is T-cells, a type of lymphocyte that matures in the thymus gland (T for thymus). T-cells orchestrate the immune system's response to fighting infection and cancer. They are divided into three groups:

- **Helper T-Cells**  
(also called T4 and CD4 cells) help other cells destroy infective organisms.
- **Suppressor T-Cells**  
Suppress the activity of other lymphocytes so they don't destroy normal tissue.
- **Killer T-Cells**  
Recognize and destroy abnormal or infected cells.

The help T-cell count (or CD4 count) determines the health of the immune system and how well it is holding up in the fight against HIV. The CD4 count is also helpful in figuring out when to start anti-HIV therapy. Too few helper T-cells mean that the immune system no longer functions properly.

The normal CD4 count is between 500 and 1500 cells per cubic millimeter of blood. In the absence of anti-HIV treatment, the CD4 cell count decreases, on average, about 50 to 100 cells each year. AIDS-related diseases (opportunistic infections) such as *Pneumocystis carinii* pneumonia can occur if the CD4 count falls below 200. Numerous other infections can occur if it drops below 100 cells.

Used in combination with viral load testing of plasma HIV RNA, the CD4 cell count helps figure out when to start anti-HIV therapies. Most experts agree that therapy should be started when the CD4 count is 350 or lower. Antiretroviral therapy involves the following four classifications of drugs.

## **1st Defense: Entry Inhibitors**

In order for HIV to bind to T-cells, the proteins on HIV's outer coat must bind to the proteins on the surface of T-cells. Entry inhibitors (including fusion inhibitors) work by attaching themselves to proteins on the surface of HIV and T-cells. This attachment prevents HIV from binding to the surface of T-cells and gaining entry into healthy T-cells.

Some entry inhibitors target the gp41 or gp120 proteins on HIV's surface. Some entry inhibitors target protein or receptors on a helper T-cell's surface. Enfuvirtide (Fuzeon, T-20) is the only approved drug in this classification. It targets the gp41 protein on HIV's surface.

## **Entry Inhibitor Drugs**

Enfuvirtide (Fuzeon, T-20)

## **2nd Defense: Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)**

Once HIV penetrates the surface, it copies its own genetic code into the helper T-cell's DNA. In this way, the cell is then "programmed" to create new copies of itself. HIV's genetic material is in the form of RNA. In order for it to infect helper T-cells, it must first convert its RNA into DNA. This conversion process requires the enzyme called reverse transcriptase.

Reverse transcriptase is used by retroviruses to transcribe their single-stranded RNA genome into single-stranded DNA and to subsequently construct a complementary strand of DNA, providing a DNA double helix capable of integration into host cell chromosomes.

NNRTIs or "non-nukes" attach themselves to reverse transcriptase. This prevents the enzyme from converting RNA to DNA. In turn, HIV RNA cannot be incorporated into healthy T-cells, and prevents the cells from producing new virus.

## **NNRTIs Drugs**

- Delavirdine (Rescriptor)
- Efavirenz (Sustiva)
- Nevirapine (Viramune)

## **3rd Defense: Nucleoside Reverse Transcriptase Inhibitors (NRTIs)**

NRTIs or "nukes" affect the RNA and DNA conversion process also. Nukes contain faulty versions of the building blocks (nucleotides) used by reverse transcriptase. When reverse transcriptase uses these faulty building blocks, new DNA cannot be built correctly. In turn, the defective or mutant DNA cannot be incorporated into helper T-cells and prevents the cells from producing new virus.

## **NRTIs Drugs**

- Abacavir (Ziagen)
- Abacavir+Lamivudine+Zidovudine (Trizivir)
- Didanosine (Videx, ddl)
- Emtricitabine (EpiVir, FTC)
- Lamivudine (EpiVir, 3TC)
- Lamivudine+Zidovudine (Combivir)
- Stavudine (Zerit, d4T)
- Tenofovir DF (Viread)
- Zalcitabine (Hivid, ddC)
- Zidovudine (Retrovir, AZT, ZDV)

## **4th Defense: Protease Inhibitors (PIs)**

After HIV penetrates the surface and is incorporated into helper T-cells, the cell produces a long strand of genetic material that must be cut up and put together correctly to form new copies. Cutting up this strand requires a scissor-like enzyme called protease.

PIs block this protease and prevent the cell from producing new viruses.

## **PIs Drugs**

- Amprenavir (Agenerase)
- Atazanavir (Reyataz)
- Fosamprenavir (Lexiva, 908)
- Indianir (Crixivan)
- Lopinavir+Ritonavir (Kaletra)
- Nelfinavir (Viracept)
- Ritonavir (Norvir)
- Saquinavir (Fortovase, Invirase)

## **Summary**

Advances in antiretroviral drug therapy have added years to the life expectancy of patients with HIV. The four classifications of antiretroviral drugs act differently to block the replication of HIV. Entry inhibitors prevent HIV from penetrating the surface of healthy T-cells. Nukes and non-nukes block HIV incorporation of its RNA into healthy helper T-cells. PIs block infected cells from producing new viruses. These drugs are often used in combination, thereby, providing multi-layered defenses against a relentless invader.

Sources:

1. [www.aidsinfo.nih.gov](http://www.aidsinfo.nih.gov)
2. [www.aidsdrug.com](http://www.aidsdrug.com)

# Quality Assurance: Personal Success and Accountability

By Jim D'Amato, Ph.D., HCLD, QA(RAB)  
QA Coordinator, Senior Scientist

**Accountability** is a key value not only in terms of ICARE, but it also is the key to our personal success. Taking responsibility for our actions permits us to take charge of our lives and set us on the path to success.

**Accountability** is not to be feared because it entails responsibility, but it should be embraced because it provides us with an opportunity to distinguish ourselves in all that we do.

## Our Quality Management System (QMS)

is based on our being accountable for what we do each day to assist our internal and external customers. It not only provides a mechanism to correct and prevent problems, but it more importantly fosters process improvement, which is essential for the long term success of our processes and achieving high levels of customer satisfaction.

## Accountability

sometimes is a little scary because it means we will be held responsible for what we do. However, we should be consoled by the fact that we practice our

## I-CARE Value System

so that even when we make a mistake, we can be expected to be treated in a fair, respectful and professional manner.

The emphasis of all corrective actions will be placed on how we can correct and prevent the non-conformance or deviation, and not who is right or wrong. Corrective, preventive actions and process improvements are not directed at the person but rather to the defective process. It is our responsibility to do our best to implement the improvements, and if we are

sincere in our actions, the results will be effective and appreciated by all concerned.

We should also look at accepting

## Accountability

for our actions as a means to distinguish ourselves. Because it is only through these actions that we acquire essential skills and receive appropriate credit for our contributions. As a result, we should embrace

## Accountability

as a means to improve our skills and careers, as well as helping our company achieve high levels of success through meeting and exceeding internal and external customer expectations.

If you incorporate

**Accountability** into your personal and professional life your harvest will be great because you get out of a process what you put into it and that applies to both personal, QMS, and corporate success.

### COMPANY EVENTS DATES TO REMEMBER

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**Upcoming MANNA CENTER Food Drive**  
**Salvation Army Coats-Outer Wear Drive**  
**11/8 through 11/30**  
**PSD Holiday Luncheon**  
**12/16**  
**GM's Open House Rothgeb**  
**12/20**  
**Holiday Party – 1-22-05**  
**More details to follow**

## Ethics and Integrity at McKESSON:

by John Hammergren

Chairman and CEO, McKesson (A reprint of John Hammergren's letter distributed to employees September 15, 2004)

The strength and reputation of McKesson is based on our commitment to the highest standards of business conduct in our relationships with each other and with our customers, suppliers, and shareholders. While I believe this has always been a top priority, never has there been a more important time for us to guard and sustain our commitment to our ICARE Shared Principles and our Code of Business Ethics. McKesson's Code of Business Conduct and Ethics provides each of us with the guidance to make appropriate decisions when we are faced with ethical issues or policy-based questions. Our ICARE Shared Principles

**Integrity, Customer-centered, Accountability, Respect and Excellence** – remind us of the values we share.

It is important for you to speak up if you become aware of an illegal, unethical or unsafe situation within the Company. If you have concerns or questions regarding such a situation, please discuss the matter with your supervisor, your company's compliance officer, HR representative or Len Patterson, Associate General Counsel in the San Francisco Law Department, who can be reached at

1-888-475-4358. The McKesson EthicsLine is available 24-hours a day, seven days a week, and connects you to a professionally-staffed call center, operated by Global Compliance Services. You may remain anonymous when calling.

Our commitment to lead the healthcare evolution, by delivering the best products, services and business solutions to our customers is built on the foundation of our ICARE values and our Code of Business Conduct and Ethics. Thank you for your assistance in ensuring that this foundation remains strong and unshaken.

# October is National Quality Month

by Ted Miller, Sr. Vice President, Quality Assurance

October, 2004 is the 20<sup>th</sup> anniversary of the National Quality Month (NQM) campaign which has been administered by the American Society for Quality. The NQM campaign has been a catalyst for an increased attention to performance excellence and encourages individuals and organizations in the manufacturing, health care, government, education, and service sectors to focus on strategic importance of quality and continuous improvement.

NQM began in 1984 with a joint resolution by Congress and a proclamation by President Ronald Reagan.

*“A commitment to excellence in manufacturing and services is essential to our nation’s long-term economical welfare. Quality in manufacturing and services will contribute to increased productivity, reduced costs, and consumer satisfaction.*

*Improving the quality of American goods and services depends upon each of us. Individual workers, business managers, labor leaders, and government officials must all work to promote a standard of excellence in the public and private sectors.”*

Proclamation 529,  
04 October 1984  
President Ronald Reagan

Our compliance with cGMPs and application of quality management principles and techniques at McKesson BioServices has contributed to near flawless operations at our facilities. Quality Assurance routinely tracks quality system indicator failures and provides reports of such in monthly QA and Executive Committee meetings.

In regards to shipping errors, we routinely perform at an error-free rate of greater than 99.9%. This was true in 2001, 2002, 2003, and continues in 2004.

Through the first eight months of 2004 our operations have shipped 64,853 orders with only 14 attributable (non-conformance) errors. This equates to an error-free rate of 99.98%, or 216 errors per every million orders processed.

Our Clinical Research Products Management Center has shipped 5,498 orders consisting of 10,552 line items without a single non-conformance through the first eight months of 2004!

While our shipping non-conformance is extremely low, it is important to note that even a single error may have an enormous impact on our business. While it is nice to tout to our clients this worthy rate as an example of our dedication to attention and detail, what if you’re that client that we made a critical non-conformance in processing an order for yesterday?

It’s only natural for this client to ask, **“What have you done for me lately?”**

Let’s look more closely at a 99.9% error-free rate. Is it good enough? If 99.9% is good enough, then:

**Two million documents** will be lost by the IRS in one year.

**22,000 checks** will be deducted from the wrong bank accounts in the next 60 seconds.

**12 newborn babies** will be given to the wrong parents each day.

**107 incorrect medical procedures** will be performed by the end of the day.

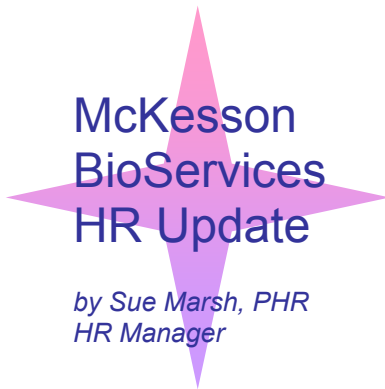
**880,000 credit cards** in circulation will have incorrect information on their magnetic strips.

As a professional services organization,

**customer satisfaction**

is one of the key measurements of our success. We must all renew our commitment to our customers and to provide them service and operating excellence in everything we do.

For October, 2004, and for that matter, for each and every month, **our goal** should be **no Customer Complaints.**



## ANNIVERSARIES

McKesson BioServices wishes to express its appreciation to those employees in the months of August, September, and October who have provided the company with years of dedicated service.

### Fifteen Years

Brian Gass, Government Operations

### Ten Years

Andy Staff, PSD

### Five Years

Maria Drapas, NIAID-Reg  
Nancy Pulido, DMID  
Lahna Jones, WRAIR-IL  
Ponder Thompson, WRAIR-IL  
Elizabeth Sewell, PSD  
Alex Gonzalez, WHI  
Cheryl Osborne, Sales & Marketing  
Juliet Villareal, PSD  
Kamal Sabir, SD  
Neeraja Putta, CRPMC  
Peter D'Orazio, PSD

## BIRTHDAYS

Happy birthday to those born during the months of August, September and October.

### August

Maureen Connolly, CAR  
Barbara Cook, QA  
Michelle Dorsey, NCIF  
Heidi Strauss, PSD  
Bryan Johns, PSD  
Kenneth Fatinikun, CAR  
Neil Johnson, IT  
Michael Hussain, QC  
Michael Murabito, CAR  
Kimberly McKinney, NCIF  
Scott Hixon, BSD  
John Pelosi, Cranberry/SERPACWA  
Binh Hoang, CRPMC  
Cheryl Osborne, Sales & Marketing  
Jeffrey Wilks, WRAIR-IL  
Sneh Bhansaly, CAR  
Shannon Matthews, NCI-CR  
Zebedee Okoye, NIAID-Reg  
Judith Judkins, PSD  
Janice Comolli, NIAID-Reg

Ben Semiatin, CRPMC  
Stephanie Clemens, PSD  
Leroy Smith, NCIF

### September

Bhavna Khilnani, IT  
Wally Merritt, NIH-ARP  
Chau Le, NCI-CR  
Steve Lindenfelser, BSD  
Juncara Simpson, PSD  
Mariela Gonzalez, BSD  
Sue Marsh, HR  
Byron Valencia, WHI  
Ivan Valencia, BSD  
Katherine Busa-Babay, Contracts  
Jennifer Benkstein, DCP  
Amanda Miller, CAR  
Jay Shukla, PSD  
Imelda Feludu, NIAID  
Regulatory Affairs  
Eric Shields, WRAIR-IL  
Chuck Gambriell, Facilities

### October

Phil Baird, Business Development/Government Operations  
Joa Haas, Sales & Marketing  
Brian Sweeney, BSD  
Sally Farley, CAR  
Dennis Smith, PSD  
Ifeyinwa Okoye, Validations  
Butch Miller, NCI-CR  
Thelma Gaither, NIAID-Reg  
Ponder Thompson, WRAIR-IL  
Solomon Bhaskarla, IT  
Luis Aguirre, BSD  
Richard Frome, NIDDK  
Jaime Pulido, NCI-CR  
Jay Lopez-Gonzalez, NCI-CR  
Mendy MA, Finance  
Willy Pirir-Rojas, PSD  
Analytical Lab  
Anita Dopkosky, Sales and Marketing  
Gloria Singletary, Sales and Marketing  
Anna Alger, CAR  
Paul Smith, NCIF  
Lahna Jones, WRAIR-IL  
Kamal Sabir, PSD  
Nancy Pulido, DMID  
Zorbari Wikina, NIAID  
Regulatory Affairs  
Geovana Penso, NIH-ARP  
Paul Sprout, IT  
Linda Antonishek, PSD  
Aleina Surratt, QC  
Robert Hutchinson, NCIF  
Bill Dillon, CRPMC  
Daniel Interiano, NCI-CR  
Carmen Meeks, NCIF

## PROMOTIONS

We wish to congratulate the following people on their recent promotions:

Joy O. Adigun, Scientist, NIH-ARP  
Kim Stulz, Facilities/Reception Coordinator, CORP  
Peter D'Orazio, Pharmacist Manager, PSD  
Miguel Flores, Repository Technician III, NCI-CR  
Ivan Valencia, Repository Technician II, BSD



1-22-04 NEO Class  
Back: Eric Shields, Barbara McGuire.  
Front: Alma Ritz, Elizabeth Meehan.

## SPOT AWARDS

We wish to congratulate the following employees on their recent spot awards:

Michael Murabito, NCI-CAR  
Carrie Nichols, Contracts  
Beth Mobley, Contracts  
Tselaine Smith, DCP  
Susan Muhr, DCP  
Jeff Wilks, WRAIR-IL



3-25-04 NEO Class  
Back: Calvin Woodley, Steve Ferrell, Kenneth Fatinikun. Front: Dave Thomas, Beth Trainer-Mobley, Jim Leinbach, and Jim Gerhadt.

## NEW FACES

We wish to welcome several new employees to our growing staff: **Tamika Richardson**, originally from Wilmington, NC (by the sea) joined McKesson as a Compliance Specialist at NCIF. She earned a BS in Biology from East Carolina University and moved here from Charlotte, NC where she had been a Quality Management Representative for BioLife. Her hobbies include surfing the Web for new and exciting things, reading, eating out at nice restaurants and gardening.



6-9-04 NEO Class  
Back: Jonathan Zotalis, Ozlem Mandaci, Dorothy Bunn. Front: Michael Megargee; Yvonne Lee.

## Other employees who joined the Company include:

Paul Sprout, IT Support Specialist, IT  
Jonathan Wald, Database Engineer, IT  
Quianna Burton, Medical Writer/Editor, NIAID-Reg  
Andrea DeSanti, Director of Business Development, Bus Dev  
Monica Ross, Inventory Associate, NCI-CR  
Teddy Negash, Pharmacist, PSD  
Rotimi Oyekanmi, Quality Control Technician, QC  
Jay Lopez-Gonzalez, Repository Technician, NCI-CR



8-11-04 NEO Class  
Back: Lakshmi Narasimhan, Brenda Knox, Jose-Miguel Carrillo. Front: Laurie Russell, Jennifer Berkstein.



9-9-04 NEO Class

Back: Andrea DeSanti, Monica Ross.  
Front: Tamika Richardson, Quianna Burton.

(Photos listed left to right in rows)



10-6-04 NEO Class

Back: Jay Lopez-Gonzalez, Rotimi Oyekanmi, Vinita Oswal. Front: Jennifer Porschen, Niema Osman, Teddy Negash, Leatrice Martin-Stebbins.

## FAREWELLS

Employees who have left the company are:

Stephen Ferrell, QA  
Javier Suarez, Validations  
Marjorie Tellier, NIH-ARP  
Sameera Rangwala, Bus Dev  
Reta Kenter, IT  
Scott McAtee, IT  
Anthony Villardo, P&L  
Jerome Carter, Facilities

## HEALTH AND NUTRITION INTERPRETING YOUR CHOLESTEROL AND LOWERING YOUR HDL

By Jim D'Amato  
QA Coordinator, Senior Scientist

Doctors no longer predict your chances of suffering a heart attack by how elevated your cholesterol is. They use a ratio between your HDL cholesterol and your LDL cholesterol. Here's a simple guideline to help you interpret your own numbers.

H stands for healthy, to help you remember that HDL cholesterol is good; and L stands for lousy, so LDL cholesterol is bad. The good HDL cholesterol carries cholesterol from your bloodstream to your liver where it can be removed from your body. The bad LDL cholesterol carries cholesterol to your arteries where it forms plaques. The good HDL cholesterol protects you from the bad LDL cholesterol, so if your LDL is 100, you need at least 50 HDL to protect you. If your LDL is 140, you need at least 65 HDL to protect you. However, an LDL over 140 should be lowered, no matter how high your HDL is. Current recommendations indicated that an HDL 50 is required.

You can lower your LDL cholesterol by restricting your intake of saturated and partially hydrogenated fats and reducing your intake of calories. If your good HDL cholesterol is below 35, you are at increased risk for heart attacks. You can reduce chances of suffering a heart attack by two percent for every mg/dl rise in HDL.

To raise HDL cholesterol, run at least seven miles a week or burn at least 1200 calories with exercise per week. Lose weight. For every pound of fat lost, expect a one percent rise in HDL. Exercise before you eat fat. A study at the University of Missouri shows that exercising regularly before eating high-fat meals raises HDL cholesterol considerably. Exercise stimulates the fat-clearing enzyme, lipoprotein lipase, which drops triglycerides to produce more HDL cholesterol.

Don't smoke. A study at Vanderbilt University showed that within just one week of quitting smoking, HDL levels increased by seven points, and limit the intake of sugar, flour, potatoes, and white rice. Foods that cause a spike in blood sugar drop your HDL cholesterol. You raise HDL by exercising and avoiding refined carbohydrates.

## MCKESSON HAS HEART

by Shannon Matthews,  
NCI-CR/Social Club

We kicked off the summer with our Summer of Fitness campaign, informing employees of the benefits of exercise and proper diet. This is the same message of the American Heart Association's annual Heart Walk, which McKesson supports with a matching gift for employee participants. This year's walk was held on Saturday, October 16<sup>th</sup>. The 3-mile walk began at Freedom Plaza and took us passed major museums and other Washington, D.C. landmarks. After the walk, we received healthy sandwiches by Subway and "goodie-bags" from Reebok.

In addition to the walk, we were able to raise funds with the Buy-A-Heart campaign. Hearts were sold at each site, decorated by employees and then displayed. This year each person who purchased a heart was entered in the raffle to award 10 "mystery prizes".

Thanks to the generosity & big hearts of our McKesson employees, we were able to raise over \$1000 dollars. "Thank you" to the walkers, those of you who purchased hearts, and the employees at each site who assisted in selling hearts. All of your efforts are appreciated. I look forward to having more employees join us for next year's Heart Walk.

## Low Fat Bean Pepper Salsa

1 16 oz. can small red beans  
1 10 oz. can corn

2-4 tablespoons hot red relish to taste  
1 Bunch chopped green onions  
1 Large sweet red bell pepper chopped

Mix all ingredients together and chill.  
Makes about 3 cups

## Under the Client Spotlight ...

### Meet Jun Lee, Associate Director of Packaging and Labeling

by Cheryl Sollars, IT Helpdesk and Communications Committee Member,  
and edited by Pat Hindes, Marketing Manager

Jun Lee is more than just a pharmacist at McKesson BioServices, he is nearly a celebrity, as it is his picture McKesson BioServices uses to demonstrate our Pharmaceutical Services Division (PSD) clinical supply management services of clinical trial materials. His photograph has been seen in various marketing materials and formats by thousands of prospective clients over the last three years as part of our overall marketing strategy.

“With the rollout of the new McKesson logo three years ago, Jun, along with other employees, helped us photograph our unique services, which I believe is a positive endorsement to genuinely market BioServices. It is not unusual for clients to stop by the Sales and Marketing booths at all the various trade shows where we exhibit, smile, and immediately recognize Jun from visiting our cGMP facility, who tell us about meeting Jun during audits and client qualification visits. It definitely opens up opportunities for our sales staff to talk with the client about current business needs. The trade shows we attend attract international clients. Jun’s photo helps draw in prospective clients visually who are not familiar with our specific services.” responded Pat Hindes, Marketing Manager, BioServices. “To me the employee photographs capture the essence of McKesson BioServices and Jun is a major part of it.”

With the recognizable face of McKesson BioServices, Jun Lee’s job changed to the new Associate Director, PSD Packaging and Labeling on July 1, 2004. This change is after almost eight years as a pharmacist in PSD’s warehouse operations. While his day-to-day role is changing, our clients will still be able to appreciate his advancement in the Packaging and Labeling services area of our business. Jun first came to McKesson BioServices as a staff pharmacist on the NCI Clinical



Repository contract, and then slowly became involved with the commercial side of the business in the PSD repository, known as BioServices, PSD.

Jun describes the new role as that of a traffic controller, which requires coordinating the dates and times and specific labeling requests of the clients. PSD’s Packaging and Labeling staff mostly work with cancer therapy and AIDS therapy pharmaceuticals for both government-funded and commercial clients.

Although a little nervous about taking the position previously held by Patrick Benson, Jun was not sure what exactly to expect. Bobby Hughes, Director of Clinical Operations says, “I definitely feel we made the right choice because the transition has gone very well.” According to Jun, Associate Director of Packaging and Labeling his new role is much more structured than being a Pharmacist Manager in PSD’s warehouse operations. “It has taken me some time to get used to it, but I’m truly

grateful for inheriting such a good staff.” He says that “In the several months that I have worked with them, one word seems to come to mind...TEAM. Our team has had a trying four (4) weeks of production runs, and during that time, the entire team was willing to pitch

in and get the job done. With me being new to the job, I was not able to help them out as much as I could have but it wasn’t necessary. Sure, the TEAM has some differences, but when crunch time rolls around they put aside their differences and got the job done. It alleviates a lot of the stress that goes along with taking a new job.”

Jun says that recently his team was able to keep a lot of clients happy even though many of the clients’ requests came at the last minute. “Depending on how detailed a client’s request is, McKesson BioServices’ PSD’s Packaging and Labeling team are capable of packaging between 2,000 to 3,000 bottles a day. Our goal,” says Jun “is to maintain high quality in everything we do.”

According to Jun, the trick to high productivity is to schedule just the right amount of project work for each team member every day for balance while at the same time building in extra time to make sure all the projects remain scheduled.. This helps

ensure everyone is satisfied with the outcome, both internally and externally.

Prior to working at McKesson, Jun worked in retail pharmacy. After five years of pharmacy school, Jun worked in both a hospital and nursing home settings, but found this type of work a little depressing for him. He decided to try retail pharmacy, where he worked for about seven years and became the manager of a 24-hour CVS pharmacy in Langley Park where he met his wife, Chiyon Lee, who is also a pharmacist.

Jun says that being a manager, seemed to accelerate the burnout process. When Packaging and Labeling are having an unusually stressful or bad day, Jun reminds his staff, many of whom have also worked in retail, that a bad day at McKesson is no where near a bad day in retail pharmacy, which can be physically and mentally draining. This is true especially during the flu season. Jun says his wife, Chiyon Lee, does enjoy retail pharmacy and interacting with the customers.

Jun is a second generation pharmacist, and comes from a family of pharmacists and engineers. His mother is also a pharmacist, and she owns her own store. The rest of his family includes his dad and two brothers, who are engineers. Growing up Jun felt he had two options-pharmacy or engineering. He says he chose pharmacy because of his mother’s influence.

Jun resides in Clarksville, MD with Chiyon Lee and his two children Kristina, age 8 and Brandon, age 6-pharmacists in training?

## Charitable Walk

By Shannon Matthews  
NCI-CR/Social Club

McKesson employees participated in two charitable walks to benefit the Crohn's & Colitis Foundation of America (CCFA). The walks were held on Saturday, Sept. 18<sup>th</sup> in Meadowbrook Park, Chevy Chase, MD. One walk was the normal 5-10K PaceSetter Walk, while the other was the 1<sup>st</sup> annual "Strut your mutt" dog walk. A dog trainer gave a presentation for the pet owners. We were served a continental breakfast and a picnic lunch. In addition to normal awards, prizes were awarded to pet owners for the smallest dog, biggest dog, and dog that most resembled its owner. Although we were met with rain that day, the event was still a success.

Thank you all who supported the CCFA by purchasing raffle tickets and attending our Charity Bingo night. With your support and through donations, we were able to raise over \$1300.

## McKesson BioServices Hosts Fall CSSG Meeting

By Pat Hindes  
Marketing Manager, BioServices

During October, McKesson BioServices sponsored the Fall CSSG Meeting at the Gaithersburg Marriott, holding an evening reception and full day meeting. Turnout for both events were successful.

Joa Haas and Randy Dulin, InforMedix presented a scientific discussion about our new combined technology platform.

## McKesson BioServices and InforMedix Sign Strategic Alliance Agreement

by Pat Hindes, Marketing Manager

Through a recently announced strategic alliance with InforMedix, McKesson BioServices' markets, sells, and distributes a combined technology platform, integrating InforMedix's Med-eMonitor™ patient diary and medication device; InforMedix Med-eXpert™ database and patient enrollment system; and McKesson BioServices' expertise in specialty CTM packaging design and medication-distribution systems. This combination solution offers clinical trial sponsors and investigators an opportunity for improving patient-medication compliance and clinical-protocol adherence, enhancing medication safety, and lowering overall cost. To learn more about this new platform, please contact the Sales and Marketing department.

## McKesson BioServices Co-Presents at PARCS Meeting 10-8-04

By Pat Hindes, Marketing Manager

Joa Haas and Randy Dulin, InforMedix presented a scientific discussion on the combined technology platform at the recent PARCS meeting.

## McKesson BioServices Hosts Vision Center Reception at Corporate McKesson in San Francisco

By Pat Hindes, Marketing Manager

McKesson BioServices sales staff hosted an evening reception and tour of McKesson's Vision Center in June. This was well attended by prospective clients, key corporate McKesson employees, and BioServices staff members who had an opportunity to meet and learn more about McKesson's services as a whole. We appreciate the added support of Meeting Services, the Vision Center, and Corporate Communications staff members who helped us coordinate the logistics for this event.

Ric Zakour was interviewed by Meagan Carmichael, Corporate Communications, for an article that appeared in This Week at McKesson in late June. If you get a chance, look in the archives and read all about it.

Using the Vision Center to host the event was an excellent opportunity for others within McKesson to learn about what we do at BioServices as well.

## 2004 Tradeshow Events

The Sales and Marketing team exhibited at the following events, as well as attend additional training courses not listed below:

INTERPHEX 2004  
Midwest Clinical Supply Group  
ISBER  
BIO 2004  
DIA 2004  
DIA Investigational Clinical Supply Training Course  
Contract Pharma  
ISPE  
Clinical Trial Supply USA  
AAPS  
BioForum

**We'll keep you posted as the events come up.**