

ASC Inc.

ADVANCED SOLUTIONS

Our First Newsletter

Upcoming Top Events in Industry:

- Process Validation for the Pharmaceutical and Medical Device Industry
Mar 15-16 2007
Sponsor: Center for Professional Advancement, East Brunswick, NJ
Phone: (732) 238-1600
- Horizons 2007: RAPS Conference & Exhibition- San Francisco, CA, US
Mar 28-30 2007
Sponsor: Regulatory Affairs Professionals Society (RAPS), 11300 Rockville Pike, Ste. 1000
Rockville, MD 20852
Phone: (301)770-2920
- World Innovation Forum, ASQ- Orlando, FL
Apr 30–May 2, 2007
<http://wcqi.asq.org>
Phone: 800-248-1946
- Advertising, Promotion, and Labeling Conference: Marriott City Center, Minneapolis, MN, US
May 10-11 2007
Sponsor: Regulatory Affairs Professionals Society (RAPS), 11300 Rockville Pike, Ste. 1000, Rockville, MD 20852
Phone: (301) 770-2920
- DIA: 43rd Annual Meeting: Atlanta, GA
June 17-21, 2007
www.diahome.org

Welcome to **Advanced Solutions**, ASC Inc.'s first Newsletter.

The purpose of this newsletter is to provide specialized information to a targeted audience in the Medical Device, Diagnostics, Pharmaceutical, Biologics industries who are passionate to know of recent news, advances and advice that can potentially be beneficial to them.

We intend to cover topics of rele-

vance in the areas of Regulatory, Quality and Business Improvement. However, we welcome your thoughts and ideas on other topics you would like us to cover in future editions of our newsletter

We intend to publish this newsletter on a quarterly basis and mail it to our current and potential clients. If you wish to unsubscribe, you can do so by emailing us at



Six Sigma Quality in Design and Development

The concept of Six Sigma pioneered by Motorola is being utilized heavily in the industry beyond manufacturing operations. Many articles were published on General Electric Corporation's efforts in implementing Six-Sigma across its manufacturing and non-manufacturing operations. Though the tools used to implement six-sigma quality are not new, the road maps promoted by different consulting groups to sell this concept are different.

On one hand, implementation of these road maps in manufacturing usually results in some cost savings identified/realized to the company's bottom-line, thus providing management a short-term goal to achieve. It is easier for manage-

ment to rally behind such an initiative since the financial impact was tangible. Consultants are usually brought in to help Green Belts and Black Belts complete improvement projects. Rewards and recognitions are quite common for those that save the company top \$\$.

Everything should be fine and everyone should be happy all the time, right?

Wrong!! Focusing on manufacturing based improvement projects only is like squeezing the same lemon in the hopes of getting more and more juice. You can squeeze as long as you can but there will be no juice (cost savings) coming out after a while. If the management folks don't realize that they can't get anymore juice from the same

fruit and do something different, you can very well assume that they will abandon Six Sigma as a passing fad. If they do indeed realize that fact, then you have an enlightened management that can start implementing Six Sigma in areas that are growth oriented. When six-sigma quality road maps are applied properly to the design and development process, they will not only result in much larger savings to the company but also add to the company's top line due to increased sales and reduced product development cycle time. If you need assistance in this area please contact us at asc456@aol.com.

Primary Business Address
ASC Inc.
Somerset, NJ -08873

Phone: 732-422-0941
Fax: 732-422-0941
E-mail: asc456@aol.com



Management Consultants to Medical
Device, Pharmaceutical and Biologics
Industry.

www.asc-fl.com

ASC Inc., provides complete solution-oriented Quality, Regulatory and Clinical affairs consulting to our clients in Medical Device, Diagnostics, Pharmaceutical and Biologics industries. Services provided include:

- Expertise in preparation and evaluation of Regulatory, Compliance and New Product Development Systems
- Training in GMP, cGMP, GLP, GCP, QSR, ISO 9000, ISO 13485, Design Controls, Internal Auditor Training, Combination Products, Six Sigma and Product Development
- Regulatory advice and consulting support to address warning letters, recalls, protocol writing, 510(k), PMA's, IDE's, PLA/ELA
- ISO and FDA audit support
- Supplier/Contract manufacturer audit support
- Expertise in Six Sigma, Innovation and Product Development

Strong focus and expertise in Combination Products and associated Regulatory, Quality Systems, Compliance, Clinical and Product development foundations for Combination Products are also provided by ASC Inc.

FDA and INDUSTRY Highlights

1. EPA Drug Disposal Guidelines

New federal prescription drug disposal guidelines recommend mixing unused, unneeded or expired drugs with undesirable substances -- like cat litter or coffee grounds -- and tossing them in the trash in nondescript containers. Doing so should curb prescription drug abuse and protect lakes and streams from contamination, the White House and government health and environment officials said.

2. Novel Insulin Pen

Eli Lilly and Co. the Indianapolis drug maker's Memoir pen is a unique, new insulin pen, the first on the market with a memory device. The pen is for use with its top-selling insulin, Humalog.

3. Drug Eluting Stents:

The study that linked drug-eluting stents with late thrombosis is printed in the Feb. 24 issue of The Lancet. Despite documenting thrombo-

sis risk of 0.6% a year, the study authors maintain that drug-eluting stents are the best choice for some patients.

4. J&J and Conor Medsystems:

U.S. data on its CoStar II trial will be released in May. The study results will be detailed at the "EuroPCR" meeting in Barcelona, which runs from May 22 to May 25, 2007. The trial results are intended to support the company's eventual application for FDA approval of the product. The drug-coated stent turns to a bare-metal device after six months.

5. Potential for Lung Breath Test:

A small breath test, making use of colors, could ultimately "lead to an inexpensive, non-invasive screening or diagnostic test for lung cancer," according to researchers, although the test produces too many false positives at the moment. The test uses the unique chemical signature of the breath of lung cancer patients, which is measured via a colorimetric

sensor array.

6. Cancer Detection Equipment- Patent approval for Clariant:

Clariant Inc., a maker of cancer detection equipment, said it received a patent for a technology to detect rare cancer cells in blood and blood marrow. The patent covers Clariant's technology with claims for using magnification change, automation and color space transformation for finding rare tumor cells.

7. AdvaMed-FDA-Virginia Tech conference:

Dr. Andrew von Eschenbach and former FDA commissioner and CMS administrator and Dr. Mark McClellan are two of the leading speakers scheduled for the Second Annual Congress on "Global Approaches to Risk Management throughout Product Life Cycles," to be held in North Bethesda, Md., May 15 to 17, 2007.