

Green Chemistry in the Pharmaceutical Industry: A Model for Sustainability

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Disclaimer

- The content of this talk solely represents my personal view of green chemistry in the pharmaceutical industry
 - It does not represent the position of the ACS, the ACS GCI, ACS, GCIPR or any pharmaceutical industry company, NGO or governmental agency

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PhRMA Companies Mission

The PhRMA represents the leading research-based pharmaceutical and biotechnology companies in the United States. **PhRMA companies are devoted to discovering and developing new medicines that will enable patients to live longer, healthier and more productive lives.**

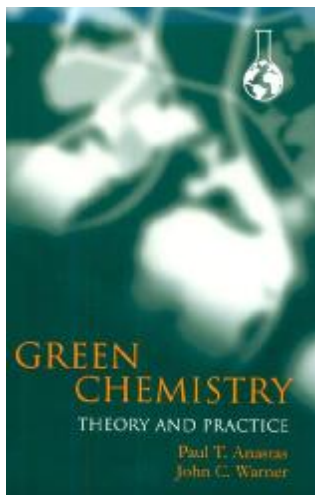
In 2006 the US pharmaceutical companies invested over \$55 billion in discovering and developing new medicines, marking the 36th straight year the industry has increased its investment in R&D

Source: PhRMA Website

BUT- Pharma Industry's commitment to improving health is not complete without a commitment to a healthy environment.

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Green Chemistry



“...the utilization of a set of principles that reduces or eliminates the use or generation of hazardous substances in the design, manufacture and application of chemical products.”

*Source: Paul T. Anastas and John C. Warner, *Green Chemistry: Theory and Practice* (New York, NY: Oxford University Press Inc., 1998). ISBN 0 19 850698 8

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12 Principles of Green Chemistry

1. Prevention
2. Atom Economy
3. Less Hazardous Chemical Syntheses
4. Designing Safer Chemicals
5. Safer Solvents and Auxiliaries
6. Design for Energy Efficiency
7. Use of Renewable Feedstocks
8. Reduce Derivatives
9. Catalysis
10. Design for Degradation
11. Real-time Analysis for Pollution Prevention
12. Inherently Safer Chemistry for Accident Prevention

Paul T. Anastas and John C. Warner, *Green Chemistry: Theory and Practice* (New York, NY: Oxford University Press Inc., 1998). ISBN 0 19 850698 8 as found on www.epa.gov/greenchemistry

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The Lay of the Green Pharmaceutical Landscape, circa 2000

- Two years after Anastas and Warner published their seminal work....
 - Some isolated examples of greening pharmaceutical processes
 - Merck (1996), BHC (1997), Roche (2000)
 - No comprehensive strategy to adopt the green chemistry paradigm evident in any pharmaceutical company
 - Belief that pharmaceutical industry waste footprint was very small compared to other sectors and the cost of doing business
 - Meeting EPA-mandated discharge permit levels was all that was needed
 - Belief that the design and manufacture of pharmaceuticals was so beneficial to mankind that some waste should be tolerated.
 - Any improvement was driven by manufacturing divisions and EH&S
 - R&D was largely AWOL
 - Glaxo was developing an very strong lifecycle analysis mindset
 - If the 12 principles were used as a RYG scorecard, most companies would have scored yellow to red in all fields

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By 2005 the Landscape Was Changing Rapidly

- Pfizer won the US EPA Presidential Green Chemistry Challenge in 2002
- Pfizer's green chemistry model, established in 2001, began to be copied by other major players
- A pharmaceutical spokesman (BWC) testified before the House Science Committee in support of the Federal Green Chemistry R&D Act in March 2004
- In 2005, Anastas and Cue formed the ACS Green Chemistry Pharmaceutical Roundtable with seed money from Pfizer and an ACS match
 - R&D, EH&S and manufacturing all participated
- ACS GCI, Lilly, Merck and Pfizer were the members
 - Met quarterly, developed a mission statement and goals
- Julie Manley was hired as a contractor to support the Roundtable.
- Roche, BMS and Merck won US EPA PGCC awards
- The recruitment of other companies to the GCIPR began
- The RT established a strategic agenda including: benchmarking, greener reactions, global reach and education

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Now (Mid 2008)

- The success of the ACS GCIPR has created copies (GC3 and a Cleaning/cleaning Products RT within the ACSGCI)
- The GCIPR has funded academic R&D, benchmarked its performance, created useful tools and sponsored education programs
- Nine companies have joined the ACS GCI in the Pharmaceutical Roundtable
 - Astra Zeneca, Boehringer-Ingelheim, GSK, J&J, Lilly, Merck, Pfizer, Schering-Plough and Wyeth
 - Other major pharma companies (Abbott, BMS, Dr. Reddys, Novartis, Sanofi-Aventis) track GCIPR and have active programs with many common components
 - ACS GCI Director Dr. Robert Peoples calls the Roundtable "one of the ACS GCI's crown jewels (C&E News, 2008)"
 - Companies comprising more than 85% of the sales of the Fortune 500 sector are known to be practicing GC
- Six companies have won US EPA PGCC Awards
 - BHC(1997), Lilly (1999), Roche (2000), Pfizer(2002), BMS (2004), Merck (2005), Merck (2006)
 - 6)Dozens of applications describing greener API processes have been received by the EPA's OPPT since 2000
 - EU awards: Pfizer (2003), Merck (2005), Pfizer (2006)

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Membership

as of June 23, 2008

AstraZeneca 

Lilly

 gsk
GlaxoSmithKline

Johnson + Johnson

 Schering-Plough

Pfizer

 **MERCK**

 **Boehringer
Ingelheim**

Wyeth

Membership is open to all pharmaceutical research, development, and manufacturing companies. The Roundtable will be strongest when all global pharmaceutical corporations are members.

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So What's Next?

- Generic drug companies
- Japanese pharma companies
- Small pharma and biopharma companies
- Drug discovery chemists
- Expand biological drugs study
- Drug delivery/dosage forms/packaging
- Pharmaceuticals In the Environment (PIE)
- Flow vs. batch processing
- Bio renewable raw materials

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