



The Chemical Consultant

Association of Consulting Chemists and Chemical Engineers, Inc.

Scientific, Engineering, Business & Management Consultants

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July– October, 2007

FUTURE MEETINGS

Please hold these dates

OCT 23

Annual Meeting

Ben's Deli
New York City

DEC 4

TBA

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ABOUT THE ASSOCIATION

The Association of Consulting Chemists & Chemical Engineers (ACC&CE) is a network of senior-level consultants with a broad range of functional expertise and many years of experience in the chemical and allied industries.

The purposes of the organization are:

To furnish support to its members as they conduct their consulting practices.

To offer prospective clients a “clearing house” which they can use to find the most qualified consultants or team of consultants whatever their particular problem may be.

This newsletter is intended to support those purposes as well as to educate prospective new members and prospective client organizations about ACC&CE, and how we can be most helpful to them.

The ACC&CE has an interactive website – www.chemconsult.org, that allows prospective clients either to input their problem or to search for those consultants most skilled in their area of concern. This website also allows prospective members to access information on the organization, including back-issues of the newsletter, meeting notices, etc. It also obviously serves as a resource for the Association's members, including allowing each member to have his/her own webpage, which benefits from the visibility of the entire ACC&CE website.

IN THIS ISSUE

In this issue, we have many items of interest to our members and other readers of this newsletter. But the first item we must report with sorrow is the passing of one of our long-term very active members, Chuck Garber, Certificate #533. We have articles by a number of our members describing some of their experiences as consultants, and we have an item describing the many activities of one of our most energetic members, Girish Malhotra, Certificate #861.

In this issue, we have an article submitted by the U.S. Chemical Safety and Hazard Investigation Board. In these increasingly difficult times, understanding the workings of this independent federal agency is very worthwhile for all of us.

Our Annual Meeting is taking place on October 23 in New York, and election of officers and some council members will take place there. We are including the slate of candidates.

Charles (Chuck) Garber, PhD, Certificate #533

We announce, with sorrow, the untimely passing of a long-term colleague and good friend, Chuck Garber. The following is an excerpt of an item that appeared in the Philadelphia Inquirer and Philadelphia Daily News on September 22, 2007. We will miss him.

CHARLES A. GARBER, PhD, founder, President, and CEO of Structure Probe, Inc., died Wednesday after a brief battle with pancreatitis. He was 66. A 1967 graduate of Case Institute of Technology, Dr. Garber was world renowned for his work in electron microscopy and polymer physics. He earned his undergraduate degree from the University of Illinois, Champaign, in Chemical Engineering. Dr. Garber was born in Rock Island, Illinois, to Morris and Evelyn Garber. He is survived by his wife, Violet; mother, Evelyn; sister, Naomi Strauss; and his brother, Melvin Garber.

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Important Information of Interest to our Members

Jennifer J. Jones, Public Affairs Specialist at the U.S. Chemical Safety Board in Washington, D.C. submitted the following item describing the workings of the board.



**U.S. Chemical Safety and
Hazard Investigation Board**

CSB Information

The CSB is an independent federal agency charged with investigating industrial chemical accidents. The agency's board members are appointed by the president and confirmed by the Senate. CSB investigations look into all aspects of chemical accidents, including physical causes such as equipment failure as well as inadequacies in regulations, industry standards, and safety management systems. The Board does not issue citations or fines but does make safety recommendations to plants, industry organizations, labor groups, and regulatory agencies such as OSHA and EPA.

CSB investigations typically take six to 18 months to complete. In the course of an investigation, the CSB gathers testimony from a broad array of witnesses, such as plant workers, managers, emergency responders, and members of the public. The CSB investigative teams also collect, examine, and test chemical samples, equipment, and other physical evidence. Accident sites are carefully studied and documented. In some cases, where there is community interest, the CSB conducts a community meeting while the investigation is still ongoing. The purpose of a community meeting is to release and discuss preliminary findings and gather testimony from members of the public, workers, and local officials.

The Board employs a staff of approximately 40 people, of whom about half are professional accident investigators. Our investigators have a wide variety of backgrounds including chemical and mechanical engineering, chemistry, law, and human factors safety. Each year, the CSB selects six to eight major chemical accidents in the U.S. and conducts thorough root-cause investigations.

The CSB works throughout the country and overseas to publicize the causes of accidents and to promote greater safety in the chemical process industries. Board members appear in the news media, deliver speeches, meet with industry leaders, and regularly brief other government officials and Congressional representatives. The CSB also develops and distributes short products such as safety bulletins, safety videos, investigation digests, and articles describing the causes of chemical accidents and measures to prevent them. These safety products are widely used in industry.

The CSB most recently released a new safety video, "Reactive Hazards: Dangers of Uncontrolled Chemical Reactions". The video features computerized animations and descriptions of four major reactive chemistry accidents investigated by the CSB, as well as commentary by two prominent chemical process safety experts. The production of "Reactive Hazards" marks the 13th safety video produced by the CSB. The videos may be viewed online in the Video Room of the agency's website, www.CSB.gov. Free DVD copies may also be obtained by filling out a request form on the website.

Experiences of our Member Consultants

**Dan Kruh, Certificate #830, submitted the following article entitled
“How a Reputation Was Born”**

I obtained my Ph.D. in organic chemistry with a thesis on the synthesis of sulfur-containing heterocycles as potential anti-radiation drugs.

Later, I found myself working for an industrial firm that made and sold polymer systems for use in electrical insulation. They were engaged in research on variations of polyimides for high temperature applications. During my first week on the job, I was assigned to solve a problem that had resisted the efforts of others for some months. The problem was that the route to a desired polyimide intermediate solution from a prepolymer stage always resulted in a useless "snotty gel".

Perhaps because I had not been trained as a polymer chemist, I proposed a solution that the lab people knew would not work (they had not tried it). When I directed the technician to put the useless gel in a 110 degree oven, he balked and told me of the dire consequences of this step. I convinced him to proceed.

To my relief and their surprise, the gel became a liquid in the oven and remained so on cooling. Subsequent patient research resulted in understanding that the prepolymer conversion at room temperature permitted electrostatic cross-linking to create the gel. The heating step disrupted the crosslinks and caused some of the polyimide rings to form. After others learned of my clever success, I became something of a sensation. This experience taught me again to trust my own judgment and that first impressions can make future success easier to come by. I then took an evening course in polymers and added polymer chemistry to my credentials.

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Experiences of our Member Consultants—Cont'd.

John M. Wetzel, Certificate #943, provided the following description of recent activities of Wetzel Chemistry Consulting, LLC.

Our startup pharmaceutical clients rapidly progress compounds toward value-building clinical validation while adding infrastructure only as they need it and can afford it.

Our experience and extensive network of contacts help our clients make good decisions and efficient progress while acquiring the necessary in-house expertise for long-term success.

Some of our pharmaceutical clients have accomplished the following with our assistance:

- Increased the efficiency and cost-effectiveness of their use of contract synthesis organizations in Asia, Europe and the U.S.
- Reduced the manufacturing cost of an active pharmaceutical ingredient (API) while eliminating technically challenging, toxic and environmentally hazardous organotin chemistry from its synthesis
- Solved scale-up issues in API synthesis
- Prepared Chemistry, Manufacturing and Controls (CMC) documents in support of two imminent New Drug Application filings

Discovered and corrected errors in a patent application that would have resulted in the patent claims being invalid for 17% of the chemical compounds in the application

Some of our most popular services are listed below:

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- **Intellectual property protection**
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- **Management of CMC for clinical development**

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Experiences of our Member Consultants—Cont'd.

Shir Thanedar, Certificate #775, submitted the following description of a recent activity of Chemir Analytical Services.

Screening for Lead in Toys – A Pilot Study

As a result of recent product recalls, there is a growing concern about the safety of children's toys imported from China. The recall of approximately 21 million toys distributed by a variety of well-known toy companies leads many to speculate about the extent of the potential contamination issue. If these large distributors are having issues, what level of comfort can the consumer have regarding the quality of product being delivered by smaller-scale distributors? In the interest of public safety, Chemir has begun a pilot study to evaluate analytical methods to screen the Lead content of Chinese made toys. Background

Paint containing more than 0.06% lead was banned for residential use in the United States in 1978 by the U.S. [Consumer Product Safety Commission](#) (16 Code of Federal Regulations CFR 1303). The U.S. Government defines "lead-based paint" as any "paint, surface coating that contains lead equal to or exceeding one milligram per square centimeter or 0.5% by weight." Some states have adopted this or similar definitions of "lead-based paint." These definitions are used to enforce regulations that apply to certain activities conducted in housing constructed prior to 1978, such as abatement, or the permanent elimination of a "lead-based paint hazard." **Objectives and Analytical Approach** In an effort to demonstrate Chemir's analytical capabilities and perform "good citizen" services, a pilot study will be performed that will involve screening Chinese made toys with painted surfaces for the presence of Lead. The objective is to evaluate EDXA as a suitable qualitative method for screening paint samples for the presence of Lead. Each paint sample will also be analyzed using ICP/OES as a quantitative method to determine levels of Lead and assist in evaluation of EDXA as a fast screening method. Chinese made toys with painted surfaces will be purchased by Chemir employees from several local retail stores for internal testing using the aforementioned methods. **Reporting** Once completed, results of Chemir's pilot study will be summarized in a report on www.chemir.com. It was also reported by FOX 2 News, St. Louis. Click [here](#) to watch the full news report.

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Experiences of our Member Consultants—Cont'd.

David W. Riley, Extrusion Engineers, FAIC, FAAAS, FSPE, FASTM, Certificate #591 submitted the following descriptions of some of his interesting experiences as a consultant.

United Arab Emirates

A couple of years ago I was requested by a Consulting Firm to work for the United Arab Emirates to develop new formulas for various PVC compounds, particularly for wires and cables. Part of the interest was in substituting tin and other stabilized PVC formulations that could be substituted for lead formulations and sold throughout Europe. Since they wanted to compare the good and the less good, I researched and constructed several formulations with several different stabilizer systems. Since I had spent seven years at Western Electric of ATT and ten years at General Cable working specifically on the formulations for lead stabilized wires and cables, this was a chore of delight.

Since lead stabilized formulations are well known to be twice as good from an aging standpoint as tin and other stabilizers, I started the UAE People out with a semi-rigid PVC formulation with proven aging of forty years—or longer. I wanted to be able to monitor them for mixing ability in their plants by rheological tests that I had invented, namely, ASTM D 3364. Their immediate response was “let’s compare this with tin stabilized PVC”. So I did some research on the best tin formulas and sent them the results. Again, I requested that they send me samples for testing for adequacy in extrudability and uniformity of sample. The Consulting firm and I then waited four months for a reply.

Their response was that they wanted a wider range of stabilized PVC formulations with emphasis on tin and calcium-zinc. They need to sell to Europe as well as the Mideast and Asia. The reason they gave was that Europe has fully rejected lead as a stabilizer despite the fact that it is much better in aging and highly un-extractable from the PVC.

I was happy to help even if the rationale was missing. I sent several other formulas to them and waited another 3 or 4 months for any payment. I never did get any samples from them and my Consulting Firm lost patience—as did I. However, they did finally pay me. But the results were not very satisfying. Obviously, their clients were convinced that the best stabilizer had some element of danger from toxicity, even though I could prove to them that there was no problem.

Amazing enough, I had another experience with American people who also were overly concerned with the toxicity of lead in humans, assuming that it could get to them through our water system.

The key factor is in the concentration of the element. While at DuPont in the middle of the last century, the highly esteemed medical staff brought in two samples, one of sodium chloride and the other of arsenic. They stated that one of the material killed a person—which one? When everyone chose the arsenic, they said that is wrong. It was the sodium chloride. The reason because the important factor is the concentration. Nothing is deadly or harmful unless the concentration is high enough.

Experiences of our Member Consultants—Cont'd.

David W. Riley, Extrusion Engineers, FAIC, FAAAS, FSPE, FASTM, Cont'd

Solubility of Lead Stabilizers in Water

I was commissioned by a client to explore the use of lead stabilizers for potable water pipes (for drinking water). After going to the authorities about it, they stated that since they had control over the use of lead in water pipes, they would devise the tests to ascertain its safety. They took the pipes that I had made with lead stabilized PVC and chopped up the pipe into a powdery consistency with a surface area at least a thousand times more surface area than the original pipe and exposed it to a water mix for 22 days at room temperature. They warned me that the world's accepted level of lead was only 100 parts per billion. I indicated that I knew that and accepted those terms.

Then, these educated people stated that because of their natural concern with the possible level of lead being toxic, they were arbitrarily lowering the level of acceptance to 50 ppb. And they might lower the level to 25 in the near future.

With criteria in mind, we ran the tests. I got only 6 ppb!!!! I was elated, until they insisted that they were already convinced that the lead at any concentration was not safe. This is despite the fact that I have had reports of the use of pure lead pipes in the homes in Cambridge, Massachusetts.

Furthermore, many of these elements that are suspected to be toxic are taken in small doses for our health, like selenium. I take it every morning with vitamin E for good health. But in large doses it is very toxic. You would not think twice about taking potassium chloride as a substitute for sodium chloride, but KCl is given in executions for lethal doses to prisoners awaiting the death sentence.

Conclusion: President Franklin Delano Roosevelt said it best in his inaugural address in 1932:
"The only thing we have to fear is fear itself."

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Experiences of our Member Consultants—Cont'd.

Girish Malhotra, Certificate #861, EPCOT International, submitted a number of emails to me illustrating a very high level of activity that we might all take a lesson from. None were appropriate to carry in this newsletter because of their lengths, but I will try to describe some of them, with contact information if our readers wish to see the full documents.

Girish sent me three articles that you may obtain from him, or by contacting Linda Townsend. They are pdf documents. They are:

1. **QBD Myth or Reality?** - This seven-page article was published in the February 2007 issue of Pharmaceutical Processing. QBD is an acronym for Quality by Design, and the article illustrates the way quality can be achieved by doing things right “from the outset of the development of new chemistries”.
2. **Big Pharma who's your role model Toyota or Edsel?** - This one-page article appeared in the June 2007 issue of Pharmaceutical Manufacturing. In this article, the author makes the point that while Big Pharma is trying to reduce their costs by outsourcing to the third world, forward-thinking organizations in India and China are not only honoring IP but beginning to create their own IP properties. It is suggested that Big Pharma needs to study the best practices of the generic manufacturers who have for many years had to compete on the bases of lower costs of production.
3. **Continuous Processes Maintain Profitability**—Published in the June 2007 issue of Drug Discovery and Development . This two-page article discusses the possible advantages to continuous processing to produce certain active pharmaceutical ingredients, but outlines the barriers that are preventing this step from occurring more often.

Girish sent me a link to a web-based periodical, PharmaManufacturing.com in which an article he has written appears. The title is “**Is IT a Catalyst for India's Drug Industry Growth?**” This article and others may be found by using the following link: <http://www.pharmamanufacturing.com/articles/2007/155.html>.

Finally, Girish has informed me that he has started a blog that he believes may be of interest to some of our readers. The address is: <http://pharmachemicalscoatings.blogspot.com/>. Girish would welcome your comments.

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