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Russ Somma – ISPE Member of the Year



Reflections on the Industry, ISPE and the World at large

Russ Somma, Ph.D., was awarded the Max Seales Yonker Member of the Year at the ISPE 2007 Annual Meeting in Las Vegas, Nevada, USA, this past November.



This award honors the ISPE Member who has made the most significant contribution to the Society during the past year.

“Russ’s leadership has enabled the Society to develop the new credential – the Certified Pharmaceutical Industry Professional (CPIPSM), the first competency-based international certification for pharmaceutical professionals covering a range of competencies from drug product development through manufacturing,” said Robert P. Best. “Russ is a major contributor to ISPE initiatives and is dedicated to raising the bar on product quality and manufacturing efficiency throughout the industry.”

In 1997, he chaired and launched another important ISPE initiative, ISPE’s Scale Up & Post Approval Changes (SUPAC) Equipment Guidance, the successful partnership with the Food and Drug Administration (FDA) that received US Vice Presidential commendation. Russ also took the lead in organizing Product Quality Lifecycle Implementation or PQLI,” said Best. “Thanks to his vision and technical leadership, industry, regulatory authorities, and the global public are likely to benefit for years to come.”

As president of SommaTech, an affiliate company of IPS, his focus is on pharmaceutical technology and helping clients achieve FDA regulated product goals for fast submission, seamless approval, cost effective product, and a secure supply chain. Throughout his career, Dr. Somma has been involved in production support, scale-up, pilot plants, as well as early and full development activities of pharmaceutical products, which include novel as well as traditional dosage forms. He has provided support for 21 NDAs in the chemistry, manufacturing and control area, from submission through the pre-approval inspection phase. Dr. Somma earned his Ph.D. in pharmaceutical science under N.G. Lordi at Rutgers University College of Pharmacy. He earned a Masters degree in pharmaceutical science and a Bachelors degree in pharmacy also from Rutgers University.

The following are Russ’s answers given in an ISPEAK interview.

“If your light shines bright enough it will be seen by many.”

ISPEAK: *How did you feel when they announced your name as the winner at the ISPE annual meeting?*

Russ: I never saw this one coming to be honest with you. When I entered the hall for the plenary session I thought it was odd to be asked to take a specific seat. This concerned me, as my sense was that I was going to be asked to thank the PQLI task team members and the commissioners responsible for the CPIP on the outstanding job they had done. While Bob Best was speaking I was frantically rummaging through my briefcase for the list of names. When he began to mention SUPAC he grabbed my attention thinking it strange to talk about that and then the realization came thanks to a well-placed nudge from my colleague Jerry Roth. I have been told that I looked like a deer in the headlights so I guess shock is a good summation.

ISPEAK: *Did you know Max Seales Yonker?*

Russ: No, I had not known Max but along with my fellow Members I was made aware of her life struggle and personal commitment at the ISPE 2005 Annual Meeting. Her husband Tom made a point of linking the products of the industry we work in and their benefit to Max's battle with cancer. Tom's shared experience has been brought closer to my own life, having had my Dad become yet another combatant in the struggle with this merciless killer. Thanks to our efforts as an industry patients do not have to hear the words "there is nothing more I can do" as often as they had in the past.

ISPEAK: *Do you know any of the previous award winners?*

Russ: How can you work within our society and not know the folks who have set the course? Jerry Roth and I have spent incredible hours putting the CPIP together. It was great to have him sitting at the table when this award was announced. Randy Perez and I had worked together at Novartis and before that at Ciba-Geigy for many years. Let me ask you this who doesn't know Jon Tomson? Dave DiProspero last year's winner and I have known each other casually as well.

ISPEAK: *Who is in your family?*

Russ: By this I assume you mean who are my technical advisors, strategy planners, chief financial officer and canine cheering section. My wife Mary Lou and I grew up in the industry and have been together since we first dated on July 7, 1977. Mary was an intern at Ciba-Geigy in our product development area where we met. She has provided guidance and has been my center for all things personal and professional. Our two children William Francis and Mary Regina are truly God given gifts and fulfill our lives everyday. Everything our children are involved with is our main focus at any given moment. William, 7, shares with me a fanatic obsession with model trains. He and I are also quite involved in scouting. Mary is 14 and an accomplished figure skater that shares with me a golf dependency. Her athletic ability is quite remarkable and a source of envy for my wife and myself. I say this based on the 5 months it took me to tame my 5 fairway wood. We have bred and raised Scottish Terriers for over 25 years. Several of them have gone on to gain national ranking in the show rink. My daughter has picked up the torch here and has become an active member of the Jack Russell Terrier Club with her our new family member Twyla. The other terriers have taken up residency on our couch in gentile retirement.

ISPEAK: *How did you get involved with ISPE?*

Russ: One person was responsible my friend Larry Kranking. The how it happened is another story and one which resulted in one of the most rewarding aspects of my professional career. In 1997 FDA issued SUPAC. While the regulatory relief offered in these guidance's were significant one bit of clarity was still needed by industry. This clarity surrounded the question of what is meant by equipment "of similar design and operating principle". Like you I thought this was an odd issue to have after all it was clear at least for me. My thoughts were that even the casual industry observer knows what equipment is similar. That was not the case so the need to form a SUPAC equipment committee in conjunction with FDA was placed in the works. Industry was asked for volunteers by ISPE. Larry took the lead then quite deftly handed off to me.

The rest is history as the similar equipment guide is still one of the most widely referred to guidance documents in our industry. Along the way our efforts were recognized by Vice President Al Gore's National Performance Review committee's "Hammer Award" for contributions to reduce costs and bureaucracy in the commercial sector.

ISPEAK: *How do you feel ISPE has helped your career?*

Russ: While at Novartis the enhancements gained in my equipment and process knowledge and applying them to our late stage developments projects were a major plus. However, what I also learned and had not been aware of for nearly 30 years was that there are many groups, which contribute to the success of these larger firms as service providers. I say this since my own work with the SUPAC committee formed many friendships. These talented people provided the atmosphere into which I found myself drawn. The bond of trust and mutual interest developed over the ensuing 7 years. Finally one infamous day I got "the phone call" from my friend and 5 weeks later I tendered my resignation at Novartis. The business, SommaTech, LLC that was started with my partners Andy Signore and Chuck Stock was the result. The atmosphere of trust and friendship is one, which drives and challenges me everyday.

ISPEAK: *What has been your best experience overall in ISPE? What are you most proud of and what is your greatest accomplishment?*

Russ: I am most proud of my family and the singular successes in each of their lives. My greatest accomplishment is needless to say my family.

The rest can be answered simply in this way. We are all industry professionals whose jobs involve moving our company's visions to market fulfillment and an improved quality of life for our patients. At times the system presents hurdles, which like myself I am sure you feel, are onerous or just plain non-value added.

Point of fact is we work within one of the most heavily regulated industries on the face of the planet. So how do you move ahead, be innovative and contribute to the body of knowledge we all go to for guidance and not quit your day job? The simple answer is to get involved at any level, which is available to us, and be open and willing to contribute your view and scientific knowledge.

Did we plan any of this to move into a position to become Member of the year? The simple answer is nope. SUPAC was a need, about which we felt strongly enough to seek out a path to contribute. The effort to embark on our most recent work surrounding the PQLI initiative on Quality by Design (QbD) for industry was a need, for which we answered "the call."

The regulators -- including Dr. Woodcock -- have called for the development of a certification program for industry professionals, which will raise the standards for folks in our area of practice. We heard the question and moved ahead with ISPE staff professionals like Jerry Roth. The take away message is this. Get involved if something is not right you can fix it and make a difference.

ISPEAK: *What is your best quality?*

Russ: I never take myself seriously. Everyone runs the risk of being educated beyond his or her own intelligence.

ISPEAK: *How do people describe you?*

Russ: This question resulted in a serious introspective moment. The answer must reside with the one person who has been my partner through everything. I asked my wife. After she stopped laughing at me she simply asked if I thought people referred to me as a teddy bear? OK, I got the point and in my own defense must say that I hold everyone to the same standards I hold myself. No candy coating and batteries not included. Enough said.

Thank You

What can I say? None of this would have been possible without my knowledge of physical pharmacy and pharmaceuticals. For this I acknowledge my teachers at Rutgers College of Pharmacy and in particular my major professor Nick Lordi, Ph.D. who believed in my ability.

My experience at Novartis and my colleagues there who helped sharpen my ability to get products to market.

The dedicated staffers at ISPE who made sure we were on track and ran interference so we could get to the end game successfully.

Most importantly the existence of SommaTech, LLC and the time devoted to ISPE are the result of the understanding and support of IPS and in particular my partners and personal friends Andy Signore and Chuck Stock.

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