In-Depth Interview with Dr. Dennis Jenke, now Principal Consultant for Toxikon Europe, on the Past, Present and Future…

I understand that after almost 35 years with Baxter, playing a leadership role in its Extractables & Leachables Programmes, your career has taken a new direction.

Yes, that is true. Certainly for the past decade or so the names "Dennis Jenke" and "Baxter" have been synonymous in the E&L world. However, if there is anything that is constant in the world it is change and an opportunity to move in a new direction presented itself.

While that opportunity allowed me to retire from Baxter, it didn't take me long to realize I was not ready to retire from the bigger mission, which has always been the practical application of good science to sustain, enhance and save lives. The question to me was how best to continue the mission, how best to use my skills, knowledge and talents to advance science and improve the human condition.

The answer came easy enough as I have had the great fortune over my career to collaborate with many equally driven, skilled and knowledgeable individuals and organizations. Although it defies the logic of mathematics, we know in science that the outcome of the collaboration between two parties can often be more than 2 times the outcome of the individual contributors (1+ 1 = 4 as opposed to 1+ 1 = 2). Therefore it is clear that my mission is best served by my greater freedom to operate in the sense of forging and developing newer and deeper collaborations.

It is for this reason that I started Triad Scientific Solutions and why I focused Triad's efforts and energies into identifying and developing collaborations with individuals and organizations that share my conviction that good science, practically applied, provides the foundation for sustaining, enhancing and saving lives.

I can hear that you are very enthusiastic about the new opportunities that the future may hold for you. Can you elaborate further on this?

Baxter's mission to sustain and save lives resonated with me from the moment that I joined the company so many years ago and became the focal point of all that I accomplished while at Baxter. As I matured and developed in my role at Baxter I recognized and understood the foundational role that good science, practically applied for the benefit of the patient, plays in achieving this mission.

Toxikon Europe NV, Romeinsestraat 12, 3001 Heverlee, BELGIUM
Tel.: ++32 (0)16 400.484; Fax: ++32 (0)16 401.304;
e-mail: info@toxikon.be; Website: www.toxikon.be

One of the major reasons I am pursuing new opportunities is the realization that the mission to sustain, enhance and save lives is as much a personal mission as it was a corporate mission and thus pursuing the mission is not just the focus of a career, it is the focus of a lifetime.

In addition to being elevating, inspiring and motivating, this mission of sustaining, enhancing and saving lives is embraced by many people. While I was at Baxter, I collaborated with many individuals and organizations who shared my passion for science and for the patient. Necessarily and appropriately, those collaborations were defined in the context of my career situation. With a new and greater freedom to operate, one can envision an even greater opportunity to forge new and more extensive collaborations.

With an elevating and inspiring mission, an innate desire to contribute and virtually limitless opportunities to collaborate, who wouldn't be enthusiastic?

The press release mentions your cooperation with Toxikon Europe, one of the leading CRO's in the discipline of Extractables & Leachables and Material Characterization. Could you explain a bit more why you chose Toxikon Europe to partner up with in building your new future?

First, let's be clear here. My "cooperation" with Toxikon Europe is not one of those "new opportunities" that I was talking about previously, as I have enjoyed a long, productive and necessarily informal "relationship" with the Toxikon Europe team for quite some time. This relationship was, and will continue to be, based on the strongest of foundations, a shared commitment to good and practical science, practiced for the ultimate good of patients. What is new about this relationship moving forward is my freedom to interact with Toxikon Europe and its clients in a more formal, rigorous and extensive manner.

Let me talk a little bit to this aspect of a shared commitment. The ultimate question to me is commitment to what and commitment to who. As business, both Triad Scientific Solutions and Toxikon Europe have financial responsibilities to its stakeholders, no different than organizations that participate in the food, cosmetic and healthcare industries. However, as science-based institutions, both Triad and Toxikon Europe have understood and embraced their responsibilities to the scientific community. Thus, both organizations and their associated members have actively advanced what is collectively and figurately termed "good science" by dedicating the necessary resources in the pursuit of "good science" and sharing the results of that effort with the scientific community so that advances made by one can be shared with and used by many.

Moreover, both Triad and Toxikon Europe understand that "good science" for science sake is not enough and that it is the practical application of good science that supports the development and commercialization of products that sustain, enhance and save lives. Thus, Triad and Toxikon Europe have focused their investigations into good science so that they produce practical outcomes that enable efficient and cost-effective product development, commercialization and support.

Toxikon Europe NV, Romeinsestraat 12, 3001 Heverlee, BELGIUM
Tel.: ++32 (0)16 400.484; Fax: ++32 (0)16 401.304;
e-mail: info@toxikon.be; Website: www.toxikon.be

As I see it, Triad and Toxikon Europe are two sides to the same coin. While we have a shared passion and mission, we have complementary skills and knowledge. Where Triad has no laboratory capabilities, one of the strengths of Toxikon Europe is its modern, state of the art laboratory facility, staffed by talented, experienced and dedicated multi-disciplinary scientists. Where Toxikon Europe has a profound capability to implement and execute studies, Triad has the experience and understanding to design, interpret, report, justify and defend studies. Toxikon Europe's excellence in tactics is complemented by Triad's long history of developing and establishing strategic standards and best practice recommendations.

Having said all this, the case for expanding our collaboration was pretty obvious and compelling.

The role of "Principal Consultant" with Toxikon Europe sounds like a lot of science, chemistry, analytics and data management will still be involved. What exactly will the role as a "Principle Consultant" entail?

It strikes me that that is a pretty tall order, kind of like asking somewhat to describe exactly the color green. But I'll give it a shot.

Let's first address what I call the "community service" side of this role. Both Toxikon Europe and I have science-based interests that we are actively exploring, pursuing and investigating. My serving as a Principal Consultant to Toxikon Europe gives me greater access to their programs and thus affords me a greater opportunity to contribute to all aspects of those programs, including their design, implementation, interpretation and reporting. Additionally, this collaboration with Toxikon Europe allows me to vet my own scientific interests and pursuits with highly trained, knowledgeable, experienced and talented individuals and gives me access to resources that are beyond the abilities and capabilities of my own Triad organization.

Moreover, both Toxikon Europe and I have a long and somewhat different experience in this industry and this collaboration provides us with the ability to share, discuss and examine those experiences with a depth and a level of detail that was not previously possible. It is hard to imagine our organizations sitting in a room together with nothing to discuss and with nothing coming out of those discussions. I am convinced that our collaboration will allow both organizations to dream big and accomplish bigger, benefiting the scientific community and industry in general and our clients in particular.

Ok, let's switch to the "business" side of this role. As a Principal Consultant to Toxikon Europe I will have appropriate access to their policies, processes and procedures. It is reasonable to expect that I will be able to provide Toxikon Europe with insights into and perspectives on such policies, processes and procedures which will lead to enhanced capabilities, improved efficiency and effectiveness, greater scientific rigor and superior robustness.

My role as a Principal Consultant to Toxikon Europe allows me to engage with its current and future clients both tactically, with regard to individual studies, and strategically, with regard to programs,

Toxikon Europe NV, Romeinsestraat 12, 3001 Heverlee, BELGIUM
Tel.: ++32 (0)16 400.484; Fax: ++32 (0)16 401.304;
e-mail: info@toxikon.be; Website: www.toxikon.be

processes and policies. Such engagement includes, but is not necessarily limited to, development, design, interpretation, reporting and justifying appropriate tactics and strategies.

Having said this, it is important to understand that this role as Principal Consultant provides a means for Triad and Toxikon Europe to work together to advance science and serve clients. Nevertheless, both organizations maintain the independence necessary to support their own objectives and to serve their own clientele.

You mentioned that you appreciate a lot the approach that Toxikon Europe is taking in the way they perform Extractactable & Leachable Studies. However, with your profound knowledge in Extractables & Leachables, gathered through your 33 year long career in this field, I could imagine that there are some areas where you could make a substantial contribution to the science and protocols of Toxikon Europe.

So let's consider this point after we acknowledge the dangers of generalization and over-simplification.

In general, however, Toxikon Europe's strength is in the analytical laboratory, where an E&L study is implemented. Thus, once an extract has been generated, Toxikon Europe is virtually unmatched in its ability to effectively and efficiently establish the identity and approximate concentration of all relevant entities in the extract.

On the other hand, Triad's strength lies in the planning of the E&L study, the selection and justification of extraction conditions, and the reporting and interpretation of the analytical results. Thus, there is a significant opportunity for Triad to step in and elevate the level of science applied to both the front end of an E&L study (e.g., experimental design) and the back end of the same study (data reporting and interpretation).

Let's consider the back-end of the E&L study specifically. Toxikon Europe's strength lies in the generation of data that provide a complete and accurate picture of a test articles extractable's or leachables profile. While this data is important, many clients lack the ability to convert the available data into information. This is where Triad steps in, specifically answering the clients' critical questions, such as "so what does this data mean to me?".

Furthermore, the universe of extractables and leachables is actually quite large, driven by the great diversity in food, cosmetic, and pharmaceutical products and applications. It is safe to say, in a general sense, that given their different experiences and roles in the E&L world, Toxikon Europe and Triad have developed a critical mass of information and understanding in certain parts of the food, cosmetics and pharmaceutical world and that these parts have both adjacencies and discontinuities. In areas of adjacencies, it is easy to imagine that our experiences will complement one another. In areas of discontinuities, it is easy to see how we both will able to learn from one another. In the end,

Toxikon Europe NV, Romeinsestraat 12, 3001 Heverlee, BELGIUM
Tel.: ++32 (0)16 400.484; Fax: ++32 (0)16 401.304;
e-mail: info@toxikon.be; Website: www.toxikon.be

building on adjacencies and learning from discontinuities will move both the Triad and Toxikon Europe organizations forward in terms of both the science and its practical application.

This situation is very much like the parable of the blind men and the elephant. In this story, several blind men are allowed to touch one part of an elephant and are then asked to describe the elephant based on the part they have touched. Of course, each man's description of the elephant is quite different as they each touched very different parts of the elephant's anatomy. The difference in their descriptions causes the blind men to quarrel among themselves as they are individually confident in terms of what they have experienced. It is only when they are reminded of the limited nature of their experiences that they are able to meld their individual experiences together to produce a more realistic picture of the elephant.

Now I am not necessarily implying that Toxikon Europe and Triad are blind. However, I am suggesting that by pooling their individual E&L experiences, Toxikon Europe and Triad are uniquely positioned to combine their individual develop and implement effective and efficient practices, policies and procedures that are science-driven and client-focused.

I also could hear that you are very enthusiastic about your future involvement in Toxikon Europe's Research & Development Programmes which are currently running. Could you explain your involvement in those R&D programmes?

It is always exciting to work with Toxikon Europe on their ongoing R&D programs because they address the two aspects of R&D that I am most interested in, establishing "good science" and making "good science" practical and applicable. Maybe even more importantly, they are not afraid to push the envelope and ask not just what is the next logical step but what is that critical leap that needs to be taken to really rocket the field forward. There is a real synergy going on here between Toxikon Europe and myself and I cannot count the times I have walked out of a meeting with them thinking either "I wish I had thought of that" or "man, I can really do something with that idea!" I am pretty sure the feeling is mutual.

While I have enjoyed working with Toxikon Europe staff members on some of their previous R&D programs, my participation was limited and largely superficial, as dictated by the organizational dynamics that existed at that time. However, as a Principal Consultant, I can jump into to these programs with both feet and work side by side with the Toxikon Europe researchers, designing, reviewing, adjusting, interpreting and reporting these programs. Instead of seeing filtered data through someone else's eyes, I will have appropriate access to the original data, which will allow me a "bird's eye view" of all the details. This is really important because I have found that one discovers the most unusual things when one is working in the grass.

The name "Dennis Jenke" is almost synonymous for high quality scientific articles in the Extractables & Leachables domain. Whether it was about the science, the concepts, the materials, the nature of the compounds or the way a

Toxikon Europe NV, Romeinsestraat 12, 3001 Heverlee, BELGIUM
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risk assessment could be performed, your scientific articles were always much appreciated and had a large impact on the Industry. Are you planning to continue these efforts and bring continued value to the E/L-community?

Absolutely and this is one of the major reasons while a close collaboration between Triad and Toxikon Europe is so important to me. You see, contributions to the scientific literature come in three flavors: reviews, opinions and technical contributions. As reviews and opinions are generally based on information that is either available in the public domain or which has obtained previously as "experiences", they can be generated once one has established a topic and once one has secured the necessary relevant public information. However, technical contributions are a different beast entirely as they generally discuss innovative and relevant research that has been recently conducted. When I left Baxter, I lost both the ability to generate the new data which is the foundation of technical contributions and access to data generated by like-minded colleagues. I know that losing such access was a great concern for me and I think it was unfortunate for both industry and the E&L scientific community. However, the collaboration between Toxikon Europe and Triad gets me back into the game, so to speak, as it provides me access to Toxikon's existing data (fully respecting the confidential nature of client data) as well as giving me access to resources for performing the new studies which produce the data that is the foundation of good science and technical contributions.

In some ways, it is like a child finding itself in a new play room, with all sorts of new toys to play with. The question is not whether to play or not, it is what toy do I play with first?

I understand that the same will be true for your participation as a presenter on many Extractables & Leachables Conferences?

Let's be honest, I do not go to E&L Conferences to speak, I go to E&L Conferences to listen. Speaking is the means of getting invited to these conferences; listening is the means of surfacing and understanding the technical and practical issues associated with the profession we have termed E&L. People ask me all the time where do you get the ideas for your publications? Well the answer is I listen. If I hear the same question over and over again, then the best way to provide an answer is to either present or publish the answer (assuming I either have or can find the answer). If a question or topic is interesting or timely or "consequential", then it's a race for me to get back to the lab or back to the literature to get my facts straight and my thoughts organized and "put them into print". When I hear someway say something that I think is particularly profound (or particularly naïve), it is an opportunity to reflect and ask "why is that right (or, why is that wrong"? If I think I have figured it out (and I think that others have not), then this is another opportunity to use the power of the pen.

Ok, so what I said is not 100% true. Beyond its technical definition, good science includes the concept of communication. Science is not good science, no matter how evolved it is technically, until it is known to, understood by, and practiced in the entire scientific community. Thus, a scientist has the dual responsibility of performing good science and then communicating that good science. Because I believe in the communication piece so strongly, I will continue to be active in E&L

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Conferences as long as I have something relevant and meaningful to talk about and as long the Conference organizers will have me.

Another point that I want to bring up is your representation in Standard Setting Organizations and Industry Consortia. For the last 15 years, you were very heavily involved in ELSIE, PQRI (Parenteral DP/Ophthalmic DP), USP, ISO 10993, and I may forget some others. Your involvement and impact in the technical guidances which have been – or – are being developed, is tremendous. Do you plan on continuing those efforts?

You may have guessed from some of my previous answers that I believe the profession of scientist carries with it certain responsibilities. One of those responsibilities is to move science forward. Another is to ensure that when science moves forward, the advances in knowledge and technology are harnessed so as to improve the human condition. This is what serving with standard setting or thought-leading organizations is all about; harnessing good science to produce standards that are efficient, effective and which appropriately accomplish their objective, which in the food, cosmetic and pharmaceutical industries boils down to producing the greatest possible user benefit with the smallest possible user risk.

Over the past decade, tremendous progress has been made with respect to growing the science and capturing it in effective and efficient standards. While some activities have either crossed or are straddling the finish line, much work remains to get these industries to the point where all the necessary standards reflect the practical application of what we term good science.

As long as the organizations are willing to have me, and as long as my science is good and relevant, I intend to be actively involved in the process of establishing best demonstrated practices and capturing those practices in meaningful standards.

Furthermore, although individuals and organizations have created so much data and information, the data is largely pigeon-holed. Thus, the really big ideas and the really big advances are stymied because no one individual or one team has access to all the data and all the information that allows them to put all the pieces together. One of the purposes for organizations such as ELSIE is to provide the means, and to a certain extent the resources, to bring it all together and make the next giant step forward. At this point it in the interview it is probably pretty clear that I support such activities 110% and will do anything I can to help them move their initiatives forward.

I would assume that, apart from the role as "Principal Consultant" with Toxikon Europe, there may be some other activities you may engage in?

As I mentioned previously, it is important to understand that while my role as Principal Consultant provides a means for Triad and Toxikon Europe to work together to advance science and serve clients, both organizations will maintain the independence necessary to support their own objectives

Toxikon Europe NV, Romeinsestraat 12, 3001 Heverlee, BELGIUM
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and to serve their own clientele. As it is clear that Toxikon Europe will perform projects and support clients independent of my involvement, so too it should be clear that working through Triad I will be involved with projects and clients independent from Toxikon Europe. For example, we talked just a bit ago about involvement with standard setting organizations and the like. This volunteer involvement requires that participants act in the best interest of "society" as a whole, moving beyond the needs and interests of the organizations that they may represent. Necessarily, then, such activities clearly fall outside my role as a Principal Consultant for Toxikon Europe and as the Chief Executive Scientist of Triad. We also previously talked about publications and presentations. While I fully anticipate that there will be publications and presentations that result from my collaboration with Toxikon Europe, I also fully anticipate that there will be publications and presentations that are fully independent from this collaboration.

You know, we started this conversation noting that I have retired from Baxter. When I reflect on all the things we have talked about, I begin to ask myself "What retirement?"

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e-mail: info@toxikon.be; Website: www.toxikon.be

About Dr. Dennis Jenke, *Chief Executive Scientist, Triad Scientific Solutions*

Dennis Jenke is the Chief Executive Scientist for Triad Scientific Solutions, a provider of science-based solutions to plastic/product compatibility challenges associated with packaging, manufacturing equipment and delivery devices in the pharmaceutical, cosmetic, food and related industries. Dr. Jenke was a Distinguished Scientist at Baxter Healthcare Corporation where for more than three decades his primary responsibility included the assessment of material/product compatibility, specifically with respect to establishing the suitability for use of packaging systems, manufacturing systems and administration devices for pharmaceutical products (for example, extractables and leachables and product ingredient binding). He has published extensively in the areas of analytical chemistry, environmental science, material/solutioncompatibility andextractables and leachables and serves as an expert reviewer for numerous pharmaceutical and analytical journals. Dr. Jenke is a member of numerous industry groups (USP, PQRI, AMMI/ISO, ELSIE) whose charter is to establish standards and best demonstrated practices in the area of material/product compatibility.

Triad Scientific Solutions LLP – Hawthorn Woods, IL 60047– USA
website: www.triadscientificsolutions.com
e-mail: dennisjenke@triadscientificsolutions.com

About Toxikon Europe NV:

Toxikon Europe is an independent, privately owned Contract Research Organisation, specialized in providing premium Extractable & Leachable Services to the Pharmaceutical Industry. Based in Belgium, Toxikon Europe supports Pharma Companies - across the Globe - in developing worldwide compliant (FDA, EMA) Testing Strategies to qualify Container/Closure Applications and Pharmaceutical Production Equipment from an Extractable & Leachable Perspective. In addition, the Toxikon group also provides Biocompatibility Testing Services (In-Vivo and In-Vitro testing), Microbiology Services and Impurity Identification Services to both the Medical Device and the Pharmaceutical Industries.

Toxikon is ISO 17025 Accredited, GLP-Certified and GMP Accredited. Toxikon is also FDA registered.

Toxikon Europe NV – Romeinsestraat 12 – B-3001 Leuven, Belgium
website: www.toxikon.be
e-mail: info@toxikon.be