

On the first anniversary of Health Robotics' CytoCare™ launch in the United States, and as the pioneer I.V. Robotics company is in Seattle for the launch of an additional new robot, i.v.STATION™, **Primus Innovations'** Katie Kimura interviewed Health Robotics' CEO Werner Rainer and Gaspar DeViedma, one of two architects behind the new robot. The objective of the interview was to review the company's performance last year, the future trends in IV Automation, the unprecedented market acceptance that CytoCare has generated during the past 12 months, and the company's expectations about i.v.STATION. Additionally, with recent competitive announcements in this industry, American pharmacists were curious about Health Robotics' reaction to other I.V. Automation companies' recent press releases.

Katie Kimura (KK). Last year, many American hospitals discovered your product CytoCare but they do not know much about Health Robotics' financial performance.

Werner Rainer (WR). Financially, Health Robotics is a very conservative company and in excellent health. We are a private company, 100% owned by company insiders, with zero debt, long-term focus, quite profitable, and cash flow positive from day one. To give you an example of our sound financial approach, all expenses from R&D activities are fully expensed as incurred, with no need for multi-year amortization.

KK. I.V. Automation companies with a long history in this sector such as IHS-RIVA and For Health Technologies have recently made some public announcements of their accomplishments last year. Our customers are curious about your company. Can you share with us your experiences over the past year and whether the worldwide launch of CytoCare has matched your expectations?

WR. I think it would be an understatement to say that we are pleased with CytoCare's results in its first year. Although we had strong confidence in our robot, we had cautiously set our expectations by looking at the performance of the two companies you mentioned, which announced combined sales of less than 30 robots over their first 20 years. During only our first year of operations, we have surpassed all of our competitors' combined 20-year sales figures.

Our "live" customers have complimented us on CytoCare's features and benefits around its verifiable high accuracy, sterility, cost savings, quick R.O.I., and no cross-contamination. As you can imagine, we are extremely satisfied with the manner hospital pharmacists and oncologists have embraced our unique and proven technology globally.

KK. These two competitors I mentioned have made unverified claims that they have products that can compete with CytoCare in the preparation of IV Oncology hazardous admixtures. Can you please share with us your views on this subject?



WR. First let me say we do not mind competition at all because we like where CytoCare stands when comparisons are made with other products. It is sometimes easier to have competition than it is the case when some people question a product on the basis that if it is such a good idea how come nobody built anything like it before? Specifically outside North America, where most procurements of technology are driven

by strict government rules, it is actually helpful when other companies participate in the bidding procurement. Foreign government officials are generally wary of awarding public tenders when only one company answers the requests for proposals or mandatory public tenders.

Gaspar DeViedma (GDV). I fully agree. Let's look at the facts on the effect of global competition: we have been awarded 100% of the decisions where we were invited to participate, and we believe we have participated in all decisions; some highly manual chemotherapy compounding solutions have already been withdrawn or de-emphasized by their companies in the North American market directly as a result of direct comparisons with CytoCare at 2007 ASHP Mid-Year Meeting in Las Vegas. Additionally when educated customers take a serious look at the 10+ year history of press releases from the two companies you mentioned, they would normally ascertain that they both have a long history of making unverified product announcements, and have only recently announced chemotherapy features. We believe these recent announcements are a direct result of the unprecedented market acceptance of CytoCare. These companies have now realized after all these years that customers are more interested in our patient-specific hazardous drugs robot than in their Batch non-hazardous I.V. automation designs, and are trying to adjust their go-to-market strategies accordingly. This "marketing hype" is normal competitive behavior on their part and fully expected by us. It is our job though to set the record straight.

KK. I understand the "marketing hype" versus "reality" argument but why do you feel so confident that CytoCare will prevail in the market over the long run?

GDV. Because we believe that customers will soon have a clear vision over the smoke

screen that these companies have attempted to build with customers in order to freeze customer adoption of CytoCare.

We obviously do not desire to educate these companies about what we believe are product flaws on their designs within a public platform such as this interview.



However, we can share our opinion that, as chemotherapy experts, we have seen both companies' chemotherapy specifications and products in public display over many years at Pharmacy Congresses. We have detailed reasons to be confident that they will not work well in the field of patient-specific chemotherapy. We believe that customers that conduct detailed due diligence will see through the smoke screens and marketing hype. We invite interested customers to ask us for technical proof as to why these companies' products should only be utilized for what they were originally designed: Batch non-hazardous IV drug admixtures, instead of patient-specific chemotherapy.

KK. Isn't it possible for these companies to retrofit their designs for chemotherapy?

GDV: Of course anything is possible given unlimited financial resources and time, but For Health Technologies has been in design mode since the 1993 while the RIVA Robot first appeared on an ASHP article in 1989¹, with not much to show for it 20 years later, so customers should make their own judgment on their likelihood of market success. In addition to the many product features in their products that are not well

¹ **Am J Hosp Pharm 46(11):2286-93 1989**

suites for chemotherapy, I recently read an article related to NIOSH alerts that cited Lucy Power, a member of IHS-RIVA's review board, and very well respected in the pharmacy community. The article² cited the opinion that RIVA's design to start with would need to be placed inside a separate negative-pressure facility built just for RIVA's use if RIVA were to ever be tested for the first time by a real customer for chemotherapy. If this opinion is correct, we believe that this does not amount to designing for chemotherapy or even retrofitting for it; this amounts to placing a huge financial burden on the customers to build separate facilities, and while it could in theory protect the environment outside the specialized facility, RIVA would fail to protect the pharmacy technician that still needs to work within the negative-pressured facility.

KK: Moving on to For Health's announcement, what do you think of the press release on IntelliFillchemo™?

WR: Well this press release together with the documented history on Dutch company MDS [Medical Dispensing Systems] presents a very interesting subject because you told us that For Health Technologies made a limited announcement last year [at least to selected customers in North Carolina, Texas, and Michigan] that they were going to purchase CytoCare from Health Robotics and resell it in North America as IntelliFillchemo [changing its name through a re-labeling process]. MDS stated in Europe that they have been negotiating with For Health for many years. It would be logical to conclude from these facts that after some years of discussions between For Health and MDS, For Health told some of their North American

customers that they wanted to market CytoCare. Since this is not possible because you market CytoCare, they now have gone back to MDS's prototype product CFM. While I understand that as a RIVA competitor of Batch IV Automation, For Health might have been tempted [and even pressured] to match the hype of RIVA's chemotherapy public announcement, in reality For Health didn't design anything new as one might conclude from reading their press release; they have just acquired the North American distribution rights for a European prototype made by Medical Dispensing Systems of Holland called CFM. For Health is simply re-labeling it as IntelliFillchemo.

KK: Being European yourselves, are you intimately familiar with this CFM prototype, which by your account is the European name for IntelliFillchemo?

WR: I am quite familiar with MDS, as this company has had a very long R&D history, similar to the other two companies mentioned before in the sector of IV Automation, and also like them, with little or no customer sales and/or "live" installations. CFM has been presented over many years at European pharmacy symposiums like GERPAC and EAHP. When Cardinal Health-Pyxis expressed to us their interest in CytoCare in 2005, they told us that they had previously rejected CFM as "technically unfit" for the North American and other global markets outside of France. Since 2005 the only technical change MDS has made to CFM is to shield it within an isolator glove box, which in our opinion, is going to make it even more unfit for the North American market, given all known and well-documented problems with isolator technology not being able to handle cross-contamination of hazardous IV drugs.

KK: Does any European hospital utilize this CFM product?

² Lucy Power quoted:
<http://drugtopics.modernmedicine.com/drugtopics/C hains+&+Business/NIOSH-to-update-hazardous-drug-list/ArticleStandard/Article/detail/401642>

WR: To our knowledge, no European hospital is using or has ever utilized CFM for chemotherapy patient doses. Outside of France, where isolator technology is overwhelmingly rejected, CFM has not generated wide interest. MDS' website has over the years mentioned 5 European hospitals that have tested CFM [University of Geneva, Hamburg University, Sint Jan Brugges, Paris V Descartes, and Curie Institute]. However, when some of our customers contacted these 5 prestigious hospital pharmacies as part of their CytoCare evaluation and purchase procurements, the response they received from the Chief Pharmacists at these hospitals was either that they had once performed a laboratory [non-patient] test of CFM and ended up not purchasing the product after the lab test or that in some cases their involvement with CFM was limited to a demonstration by the MDS' marketing staff which resulted in the hospitals not moving forward with the product. MDS' marketing hype is very similar than some of RIVA's announcements of North American hospitals signing letters of intent to buy RIVA when all these customers were doing was to sign a confidentiality agreement to see a product demonstration by RIVA's marketing staff with no decision whatsoever to buy RIVA^{3 4}. This is an example of what I earlier referred to as marketing hype and smoke and mirrors that has been exhibited by other companies in order to slow down our market growth.

KK: How about For Health's claim that their IntelliFillchemo™ (the CFM solution) offers savings of 50% over competing solutions with its announced ~\$400,000 price tag?

³ UCSF: <http://www.rivasystem.com/news-pr-2006-12-04.html>

⁴ Banner: <http://www.rivasystem.com/news-pr-2007-02-08.html>

WR: Setting aside for a moment the discussion we just had about marketing hype versus real and verifiable installations, CFM is not a fully automated solution such as CytoCare, it is just a step above manual syringe-filling solutions in the market, so it should be expected to cost just a small fraction of a total automated solution such as CytoCare. In addition, we are somewhat puzzled by its price because in Europe it has been offered to hospitals at approximately half of the price than For Health has announced in your country; \$200,000 is much more aligned with its advertised value, that is if it ever makes the transition from a prototype to a real product in use by a hospital anywhere.

KK: Let's switch topics to your new product announcement, what can you tell us about i.v.STATION? Does it compete with RIVA's and For Health's products for Batch compounding of non-hazardous drugs?

WR: Yes and no. While i.v.STATION does address the preparation, compounding, and dispensing of non-hazardous drugs, it was designed with a much distinct philosophy (in addition to very different technological advances) than RIVA or IntelliFill i.v. These were designed with Batch IVs in mind as opposed to patient-specific preparations. i.v.STATION attempts to, where possible, eliminate Batch IV preparations and therefore, the waste associated with them, which is an increasing burden especially to North American hospitals.

KK: Do you mean that an IV Automated solution generates less waste than manual compounding through its more efficient re-use of human resources and materials?

GDV: Well this is true of some solutions but this is not what we meant. While solutions like CytoCare or i.v.STATION indeed reduce waste in the manner you describe [I cannot comment on the others because I have personally never met anyone who ever

witnessed real waste reduction with IntelliFill i.v. or IHS-RIVA] what we mean is that the whole concept of Batch IVs is wasteful because many IVs are returned unused to the pharmacy and thrown away, regardless of whether they were manually or automatically compounded.

KK: Does this waste issue related to Batch IVs apply to the United States, or is it just something that you have observed in Europe or other parts of the world?

GDV: Actually, it mostly applies to the United States because there is very little production of Batch IVs outside of North America or Australia. European hospitals cannot afford the waste of Batch IV production with 5 to 9% of their respective countries' GDP devoted to healthcare. On the other hand, you spend 16% of your GDP in healthcare with a big chunk of it due to the fact that you pay medication prices that are 50% to 125% higher than other countries' hospitals. This creates the possibility of waste [and positively, also the potential for waste reduction] due to the enormous difference in pharmaceutical expenditure per acute care bed [both in personnel and materials] between the United States and other industrialized nations' hospitals. If you or your customers are interested I recommend reading the Rand Corporation study of waste of Batch IVs at hospitals in your country, where the observations of former Secretary of Treasury Paul O'Neill and his team were documented for this study. O'Neill described how IV drugs are filled in Batch mode every Monday, Wednesday, and Friday as a way to optimize the time of pharmacists. But not surprisingly, patient conditions change more rapidly than every other weekday. In fact, 40 percent of the hospital's IV solutions that are filled on Friday come back on Monday because of changes in patient conditions, and the returned intravenous solutions are simply

dumped down the drain. As you can understand Batch IV Automation does not solve this problem, only a just-in-time patient-specific IV Automation solution like i.v.STATION can help with the waste of returned items. In summary, if American hospitals want Batch IV production they should take a look at our competitors, but if they want to reduce this waste, they'd definitely be looking at i.v.STATION.

KK: If I understand this correctly, it seems that i.v.STATION has the potential of making your competitors' Batch products obsolete unless they are redesigned for just-in-time production of IVs, is this correct?

GDV: We think so but I do not believe this should be news to experts in the Pharmacy Automation sector, at least looking at both of the companies afore mentioned starting with their products around 1995 for FHT and 1987 for RIVA, and where they are today. The fact that the American hospitals have not accepted these solutions in such a long time (20+ years) cannot be solely attributed to their technical limitations or numerous delays; I believe they were designed for the large-scale production of Batch IVs, and that is a bigger problem. Just look at the needs in high-acuity patient care, which does not lend itself to Batch IVs due to, amongst other factors, the ever-changing patient conditions and physician prescribing preferences. Why would a hospital that is throwing away 25% to 40% of their Batch IVs spend in excess of \$1M in a piece of automation that continues to generate this waste? We believe there will always be the need for some Batch IV production, for example TPNs, but this is an area where we are ready to agree that we are on a level playing field with our fellow IV Automation competitors.

KK: Thank you very much for discussing these competitive concepts with us. How about if we delve into i.v.STATION specifics? I have heard people describe it as the Pyxis

of IVs or as to dealing with whatever you cannot dispense out of Pyxis or similar cabinets. Is this correct?

GDV: Again there is no black and white answer to this question. Pyxis is a good target to shoot at in terms of market acceptance, but i.v.STATION not only dispenses medications as Pyxis does for oral doses; it also prepares and compounds the IVs which is a big difference with Pyxis. Like Pyxis or other cabinets, i.v.STATION attempts to provide the best combination of centralized pharmacy control with decentralized just-in-time production and dispensing close to the patient care areas. i.v.STATION maybe implemented in the central or satellite pharmacy locations, or in nurse station [wards in Europe] or ambulatory infusion centers. Due to regulations and pharmacy practices we expect the former to mostly occur in the United States and the latter mostly in the rest of the world.



KK: How does i.v.STATION compares to CytoCare?

WR: They both include airflow engineering, HEPA filters, medication error-reduction software, high accuracy, sterility, bar-code or RFID support, flexibility in using standard IV final containers brands and sizes, ability to handle powder reconstitutions, etc. The main differences are throughput [because the steps and checks on non-chemotherapy IVs are less stringent] making i.v.STATION two to three times faster than CytoCare, modularity [the IV Bags module may be purchased and installed separately than the Syringe module], and the venting requirements, obviously due to its lack of toxicity as compared with chemotherapy.

KK: I am sure two of the questions our customers will have is when can they have it and how much does it cost?

WR: People that are interested in i.v.STATION should contact Gaspar as he personally designed this new product with our V.P. of R&D Paolo Giribona. The press release includes his contact information. We expect to release the product sometime in late 2009 or early 2010, after beta tests or validations at both American and European hospitals. In terms of its costs, we have yet not finalized the analysis and we also need to wait to make decisions on which companies are we going to select as marketing partners for this product globally. I can confidently tell you though that it should be less than half of the expense of either RIVA and/or Intelifill i.v.

KK: Thank you very much gentlemen for coming to the United States of America for this symposium; it has been an extremely interesting and educational conversation for me, I hope our customers will also be pleased to read about it.