Advent One Pty Ltd is an IBM infrastructure business partner located in Melbourne, Australia. A primary focus area of our business is the Life Sciences sector and in particular the biotech and healthcare sectors. I have been working in this area over the last two years in close alliance with IBM and would like to offer some thoughts on my experiences.

The Australian biotechnology market has been in a downward trend over the past two years and investor’s eyes have turned towards the healthcare market. Bringing drugs to the market requires a huge investment and this cuts out most companies except the major players such as Pfizer or GlaxoSmithKline.

Of the biotechs that do make a New Drug Application (NDA) submission to the US Food and Drug Administration (FDA), they will have typically spent millions on Information Technology (IT) and much of this expenses is often reactive and not planned. My experience over the past two years is that the companies lack an IT strategy to align with the different phases and ultimately the overall business plan of the company. My work in the sector has evolved as I have realized that the strategy is not merely one of supplying IT hardware and services but one that requires an intelligent structured approach of supplying strategic bundled solutions and support to fulfill the various requirements during the drug development life cycle.

Now, whilst new IT technologies tend to bring short term benefits these will not be realized in the long term without a change in existing processes and business practices. An example is the continued use of paper-based systems in the face of new IT solutions geared towards meeting regulatory pressures. So changes are needed in IT infrastructure as well as business practices.

by Jason Surendran  
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The main point of concern with IT hardware is the lack of an integrated platform that will grow with the company and more importantly as data/IP grows. Obviously, cash is the all-important factor and cash-strapped organizations often find themselves purchasing IT equipment in a haphazard way. This means companies have a mix of IT systems with different operating systems and applications. This then leads into problems with data integration and scalability as the company grows.

Over the last two years, a bulk of our work has been to identify relevant solution packages to align with the stages of drug development and marketing. This covers bioinformatics solutions at the research level to customer-relationship management systems (CRM) at the marketing and sales level. An important underlying strategy is the management of the data/content. With submission to the FDA as the ultimate goal, it is of vital importance to manage content in a format that fulfills regulatory compliance issues (i.e. 21 CFR PART 11). Data is the company’s most valuable asset and must be protected. It is important that backup strategies be in place with the relevant IT hardware. To handle the expected data growth this hardware must be able to scale as the data volumes increase. Too often solutions that do not scale are put into place and have to be replaced as data grows, meaning money and time are wasted. A suitable approach would be to start with an entry level configuration that can be added to as data requirement grows. This “on-demand” approach will be something we look to push into the market as budgets become tight and initial outlay is constrained.

Looking at some of the solution bundles we have put together starting at the discovery/modeling level. We have formed partnerships with leading molecular modeling software companies to bundle their software with IBM hardware into turnkey packages (as well as bundling open source packages) on a Linux platform, to address the very first phases of drug discovery. Other solutions that we have bundled for this early stage include reference search software and knowledge management tools. It is vital that the requirements of regulatory compliance be addressed right from the start and that a strategy for this be adopted. Our approach has been to recommend life science-specific document/content management solutions together with effective storage management software. Life science-specific content/document management packages include paraFileTM from Winchester Business Systems. Our storage bundles have varied according to the budgets of a company, solutions range from IBM’s Tivoli Storage ManagerTM to our “Biotech IPPP package” that bundles TapewareTM (YosemiteTM) software with an IBM fileserver and IBM tape backup unit.
The biotech market is becoming more globally focused in order to survive. The requirement to control costs of drug research/discovery pushes companies to form partnerships with competitors. Many of these partnerships are international collaborations among companies and government institutions. In practical terms, collaboration would go beyond simple email exchanges and teleconferences. IT can greatly enhance the options available for collaboration amongst teams across the world. IBM currently offers the WorkplaceTM suite which enables instant messaging (SametimeTM), web conferencing tools and basic document management. Having decentralized systems across sites means that an effective way to work together without having to physically travel to locations is a time and cost benefit. Minimizing the errors made by miscommunication is an immediate benefit of collaboration with the ease of arranging online meetings and online document reviews, via Workplace Teamroom™, thus ensuring that a far more rigorous quality assurance process is adhered to.

As companies grow so the requirements for handling data grows. This is where the previously mentioned scalable infrastructure plays a crucial role. Storage Area Networks (SANs) that can scale by the addition of a range of components from single hot swap disks to multi-terabyte disk drawers gives the company flexibility without the need for wholesale infrastructure changes. This building block approach applies to servers as well with infrastructure such as the IBM BladeCenter™ or IBM Cluster1350™. These server infrastructures allow servers to be added in building block fashion as and when required. A skeletal infrastructure has to be in place at start-up to allow for this growth. A proposed finance model for this approach would be a minimal payment for the skeletal architecture and further payments as “building blocks” are added.

So far I have discussed specific BioIT applications and hardware. There are the mandatory back-office applications, such as email, accountancy/finance applications, HR packages, customer relationship management software, and so on. Experienced IT staff or external consultants are needed to manage these requirements as well as the specific applications/hardware previously detailed. This is something that Advent One is looking to do in bringing the “whole package” to the market. Often scientists and specialists are too busy with day-to-day work to focus on core IT support, so this is where support from a third party company would be of benefit. The question is whether the cost of this is justified and hence an IT company with a science background that can work in partnership with the client offering specific applications, hardware, IT support, and most importantly, a company that can implement an IT strategy is the ideal fit for this requirement.
Further down the life cycle, external companies are bought into the project to push towards an FDA submission. Clinical trials require effective partnerships with a Contract Research Organization (CRO) and that entails even more data handling, security and audit issues and the inevitable collaboration requirement. Security is an area not touched on yet in this piece. Packages have to be in place and business practices have to be followed to ensure protection of patient information and research information. Various IBM products from thumbprint readers to software such as Tivoli Security packages as well as a new third party product that monitors user access are being pushed by us. The previously mentioned collaboration tool, Workplace, enables instant communication between the various parties at the trial stages. This enables clearer record keeping and hopefully produces far more accurate data.

So, as you can see, having a solid IT foundation and strategy at start-up leads to a scalable infrastructure that grows as the company and data requirements grow. Supplemented by the specific applications to align with the life cycle phases quality assurance, adherence to FDA and other such regulatory compliance requirements can be met. In the long term, the initial investment is paid off in money saved and time used efficiently. If start-up funds are minimal, as I have found, creative financing models can be employed so funds are only spent when needed in an “on-demand” approach.

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