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Trade Secrets

Collaboration can benefit the industry in myriad ways, but not without jeopardising intellectual property and regulatory compliance. John Avellanet at Cerulean Associates tackles the dilemma

John Avellanet is a successful business executive, consultant and international author. His consulting firm, Cerulean Associates LLC, provides independent IT and regulatory compliance advice to executives around the world. Prior to founding Cerulean, John was the CIO of Chrysalis Technologies, a multi-product and medical device development company and an Altria Group subsidiary. John is a FDA-trained 21 CFR Part 11 auditor, and has more than 15 years of experience succeeding in heavily regulated businesses.

Drug and product development collaborations would seem to benefit everyone, from large pharmaceuticals to start-up biotechs and eager customers. Yet there is one group increasingly at risk – shareholders. Why? Although collaborations increase innovation and speed new products to market, they also jeopardise two elements necessary for sustainable profit in the global marketplace – intellectual property and regulatory compliance.

For 2005, estimates by Interpol, the World Customs Organization and the United States Federal Bureau of Investigations and Department of Commerce place intellectual property (IP) theft from companies in North America, Europe and Japan at nearly US$600 billion, with pharmaceutical patents being frequent targets (1). Further complicating the issue is the cost of complying with a broad array of regulations around the globe. Recent studies have benchmarked the cost of compliance for life science firms in the US alone at approximately US$2 billion per year.

While the costs of compliance and discovery can be incorporated into the prices of new products, this is only a short-term remedy. IP losses and compliance challenges place the long-term competitiveness of most biopharmaceutical organisations at risk.

How then to ensure compliance and secure IP without reducing the speed and innovation benefits brought by collaborations? The answer is a proactive, flexible strategy embedding compliance early into product development while capturing intellectual property opportunities.

TRADE SECRETS AND COMPLIANCE

Such a strategy emerges with recognition of the inherent parallels between ensuring regulatory compliance and safeguarding IP. Key to this strategy is the ‘trade secret’ concept. In essence, a trade secret is knowledge (including techniques, methods, ingredients and processes) which a company takes reasonable precautions to protect. The definition of ‘reasonable’ has historically been interpreted to consist of a risk assessment (including a cost-benefit analysis), a survey of industry standard practices, and safeguards appropriate to the organisation and its product.

Compare this to the recent developments under the US Food & Drug Administration’s (FDA) global harmonisation drive: risk assessments, industry standard practice expectations, and reasonable safeguards around information integrity and validation appropriate to the organisation and its product. Seen in this light, regulatory compliance requirements are synonymous with intellectual property protection, despite differing goals. A strategy that aligns these two similar sets of requirements, while incorporating the flexibility to achieve both compliance and IP security, will provide companies with long-term bottom line improvements.

In our experience, such a strategy involves six key tactics:

- Education
- IP liaison
- Control checkpoints
- Knowledge flow agreements
- Personnel changes
- Use of five technologies

Most organisations have some semblance of each of these in place today. By taking a more holistic, strategic approach that makes use of the processes and skills already available within an organisation, plus creative use of several technologies widely available in the marketplace, a company can put this strategy into effect in less than 100 days.

INTELLECTUAL PROPERTY AND REGULATORY COMPLIANCE EDUCATION

The first tactic is to bring in the legal department to perform two high-level reviews: one on the regulations involved in the product under joint development, and the other on the development agreement between the companies. It is important to focus the regulatory session with examples of where the company is 'drawing the line' between ideation and research activities versus development under design control and other formalised rules. This needs to be clear to all individuals involved – not only the scientists and engineers, but the project sponsors, business development executives and other cross-functional members of the collaboration.

Review of the collaboration agreement should at least cover what intellectual property is (including examples of what the company considers its IP), who has ownership of IP, examples of how IP ownership can be compromised, and the concepts of confidential information and disclosure. For multi-year development collaborations, annual reviews are useful, especially as contract amendments occur and project personnel change.

INTELLECTUAL PROPERTY LIAISON

The second tactic is the appointment of an appropriate individual as the Intellectual Property Liaison for the project. This individual will need to receive a few days of more detailed training on IP, confidential information rules and patents by the legal department. We recommend selecting an individual capable of understanding both the legal and the business consequences of treating issues as intellectual property, including their disclosure (such as in a research paper). This individual will be required to make rapid judgement calls during development meetings.

The IP Liaison has five core accountabilities:

- Reviews of all project-related documents and presentations for appropriate disclosures and confidentiality/ copyright notices
- Summaries of the project, its status and current pros and cons
- Monitoring the project's information integrity and IP, working with the computer department to assign and review electronic security permissions to documents, files and so forth
- Track and inventory design information and knowledge, including the role each project member plays
- Communicating development meeting summaries to the project board and company executives

For the latter, it's important to realise that these meeting summaries are not minutes, but rather one or two paragraphs recording any confidential subjects discussed and decisions made. These summaries are crucial to patent applications and demonstrate awareness of, and consideration for, compliance risks (including patient safety, drug efficacy and so on).

CONTROL CHECKPOINTS

Control checkpoints need to be built into the development process, almost as project check-ins. Organisations already utilising a stage-gate methodology should consider expanding their 'gates' to take in intellectual property and regulatory compliance. Whether you utilise the stage-gate methodology, your own process or develop some level of project report-in structure, from a regulatory compliance and IP perspective, there are two underlying goals. First, you want to be aware of any new IP possibilities early on, when the steps to protect the IP are at their most effective. Second, it is a good idea to uncover any regulatory risks sooner rather than later. In this way, resolution is usually quicker and the issue more manageable, otherwise resolution may have a significant negative domino effect.

The cross-functional members of the stage-gate or project check-in board can then tackle the items raised offline without slowing down the project (legal assessing the IP opportunities, regulatory affairs and quality targeting the compliance risks). The contact point for each of these groups can be the IP Liaison – further minimising distractions to the development team while reviews are occurring.

KNOWLEDGE FLOW MANAGEMENT

The IP Liaison can also take the lead in creating protocols for information and knowledge management flow between the collaborating organisations, as well as guidelines for knowledge distribution back into each organisation beyond the project teams and sponsors.

Craft a joint development agreement (JDA) focused solely on information and knowledge flow. This should be written within the constraints of the legal contract, formalising the collaboration between the companies. While the partnership contract always supersedes the JDA, roles and processes from the JDA frequently become contract amendments. Key components and processes to address in the JDA are: communication; issue resolution; project reviews; roles; checkpoints or stage-gates; and other types of information exchange and decision-making arenas that should be aligned between the collaborating organisations. Ideally, consider involving someone from your records management and/or IT groups to ensure that appropriate levels of security and record retention are incorporated.

Consider placing all project documents, schedules, meeting summaries and so on, in a central repository where they become the property of all parties involved in the collaboration. Note that storing the documents in a central location does not imply across the board access. Many of the documents will be 'read-only' (or may not even be visible), depending upon each individual's role within the collaboration. In addition, having the IT department provide a regular electronic back-up, as well as periodic snapshots of the repository for long-term archival, will provide each partner protection and proof for its claims of IP and compliance.

While the JDA that governs this central repository is not a legally binding document, it is a set of operating principles and guidelines agreed upon between the members of the project teams, and as such should form part of the introduction process for any new project members, as well as provide guidance for personnel either changing roles within the project or leaving the project.

PERSONNEL CHANGE MANAGEMENT

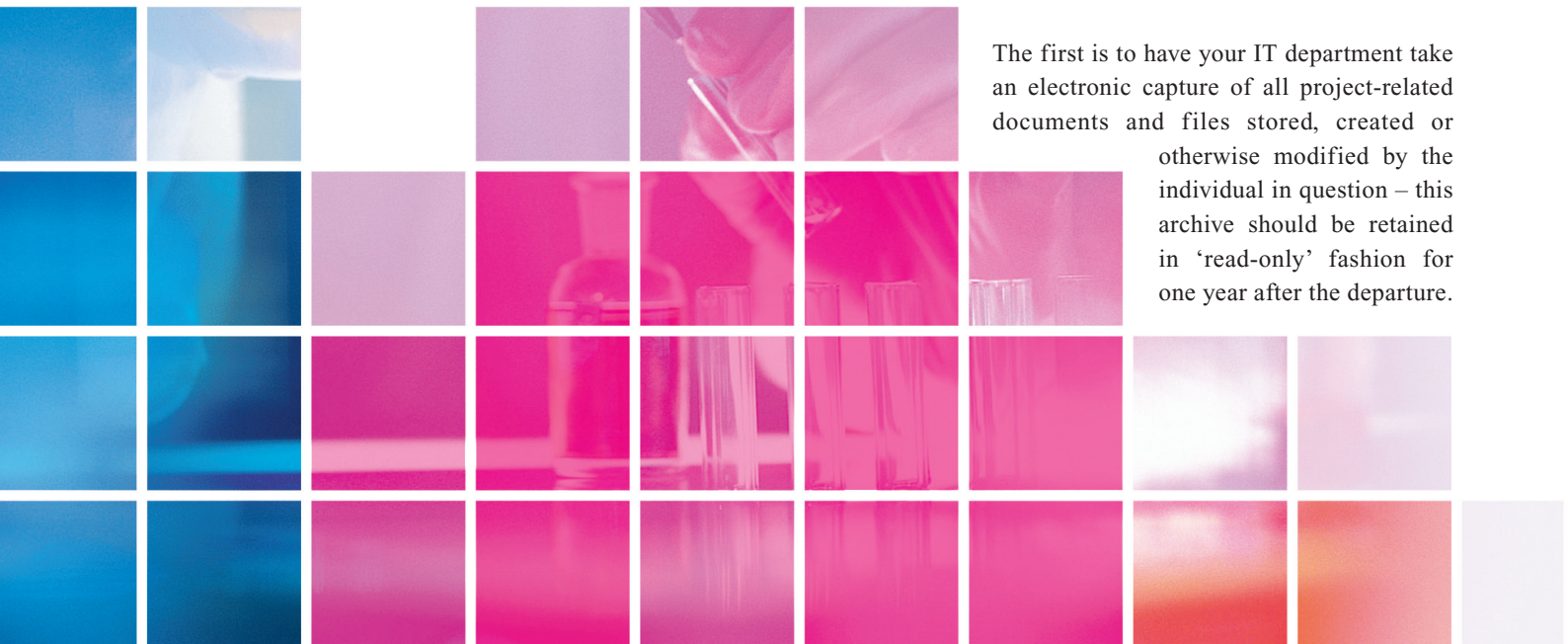
The reality is that personnel changes over time; in fact, depending on the scope of the collaboration, entire groups may come and go (in which case, you may want to examine the JDA for revisions).

5llectual property: personnel 'on-boarding' and personnel 'debriefing'. (When individuals shift roles within the project, it is often simplest to consider debriefing them on their old role and then on-boarding them for their new role, rather than creating an alternative third process.) Consider running both processes jointly through the IP Liaison and the Project Manager, as well as any appropriate individuals from other departments (such as records management or quality assurance).

The on-boarding process should include the regulatory and collaboration agreement overview, the role of the various project members (or groups), the current JDA and the overall project portfolio summary.

The project portfolio summary, typically written by both the IP Liaison and the Project Manager, is in two sections. The first is approximately 200-300 words within 12-15 sentences and is targeted toward an executive or non-technical reader. It includes: an overview of the project's goal; the differentiation of this product in development versus products already on the market; the current stage of development; and any specific IP previously or otherwise publicly disclosed (such as patents, trademarks). The second section is longer, more detailed and specifically written for the Product Engineer and Scientist. This section covers the technical and collaboration details (including the terms and conditions, a top-line summary of the JDA, where and whom to see with questions, and so forth). Debriefing departing personnel is important to prevent project teams from covering ground already tracked. There are three elements to debriefing project personnel.

The first is to have your IT department take an electronic capture of all project-related documents and files stored, created or otherwise modified by the individual in question – this archive should be retained in 'read-only' fashion for one year after the departure.



Next, the Project Manager and the IP Liaison must meet with the individual and review his or her role in the project, what was worked on, and feedback for the team, focusing on knowledge about project activities, regulatory risks or IP opportunities that the individual may have that might not be captured somewhere (simply asking is often the most effective approach). Third, ask about the possibilities the individual sees for the development effort, such as other product opportunities that have yet to be explored.

The debriefing session is not a search for hidden clues or secret agendas; rather it is an attempt to capture information one-on-one that an individual may be reticent about sharing with a larger group or may not have thought significant to the team's efforts.

Depending on the circumstance of the personnel departure from the project, your organisation may also require individuals from personnel, legal, or records management to be involved. Regardless of the nature of the departure, we recommend that both the Project Manager and the IP Liaison conduct a brief review of the IT snapshot of the individual's project files prior to the debriefing. These two individuals are in the best position to quickly identify items that warrant asking about during the debriefing.

FIVE TECHNOLOGIES TO CONSIDER

In addition to supporting electronic information reporting, security, storage and retrieval, your IT department can also provide five technologies that help protect intellectual property, aid in regulatory compliance and speed product development.

Encryption

This does not need to be elaborate; simply using compressed files with password protection can satisfy the need to minimise prying eyes (2). From the compliance standpoint, several such software tools also have built-in bit-checking capabilities as part of their compression and decompression routines, providing perfect built-in file transfer validation.

3D Printing and Faxing

Printers and fax machines that print realistic three-dimensional objects, such as prototypes, component assemblies and so forth, are perfect for rapid prototyping, particularly across geographically remote teams, but also provide good components for a product's design history file.

Collaborative, Secure Virtual Storage Space

Set up a secure site using the internet and role-based security access (for example as the Project Manager, you have access to x, y and z, but as the Product Designer, you only have access to x and y) and use this location as your centralised repository for all project reports, data and drawings that are expected to make up a design history file or other set of compliance traceability documentation.

Content Filtering Software

Despite precautions around the use of email for discussions with compliance or IP implications, the simple reality is that inevitably a disclosure or decision will initially be made during an email conversation. Using an automated filter for key phrases (rather than words) is a simple approach to help mitigate the risk. Your IT department or outsourced email vendor can set alarms that notify your IP Liaison of a potential risk.

Secured Video or Web Conferencing

While clearly an aid to speeding new product development across geographic boundaries, conferencing services can have the technical capabilities to record the session. This can be valuable for compliance and/or IP protection questions at a later date; however, all parties involved in the conferencing will need to provide written agreement to such recordings. If you choose to go down this route, our advice is to place such recordings into the shared repository.

Several video conference vendors are working on holographic video-conferencing technologies. IT organisations would do well to keep an eye on this technology, perhaps offering themselves as a beta test case.

FINAL THOUGHTS

These six tactics balance flexibility, regulatory compliance and intellectual property protection. They recognise and incorporate two key considerations: the sooner regulatory compliance is embedded in the development stage, the lower the cost; and the earlier intellectual property is identified, the greater the reward reaped.

The parallels between regulatory compliance and intellectual property protection provide executives with powerful opportunities to secure the building blocks of long-term profits in the global marketplace. ◆

The author can be contacted at
john@ceruleanllc.com

References

1. **Bush Administration Tackles Intellectual Property Theft, *Information Week*, September 2005**

2. **Examples of compression software vendors with built-in security features include WinZip® International LLC and PKWARE, Inc**