



## **Pharmaceutical Industry Project Management Group**

**Spring Meeting – 7 May 2009 – Beaumont House**

### **RESPONDING TO CHANGE, MAXIMISING VALUE OF PRODUCTS IN DEVELOPMENT**

**Moira Thomson** (Fulcrum Pharma) and **Heidi Towers** (Medimmune)

#### **Executive summary**

High performance communication is becoming increasingly important for the future of our industry.

Small companies looking for investors and partners have to think hard about how their assets and their operation will be perceived by finance-oriented executives who have many other firms presenting to them. All of a company's managers and staff need to be aligned to the most powerful, accessible and well thought-out messages.

Venture capital firms are under increasing pressure for returns on investment. They are looking for clear, persuasive communication that demonstrates that a company has convincing, real-world market positioning for its assets. Also that they have a business-oriented, professional team in place to manage ongoing projects.

For small and large firms, multi-national teams, networks of suppliers, partners and alliances are a reality in this day and age. This increases the risk of miscommunications, mis-matches between different cultures/ways of working and real issues of trust. It's essential for players in these networks to acknowledge the style and cultural differences, take time out to talk across teams and build ways to communicate and collaborate in the most effective way for all.

With regulatory agencies throughout the world seeming to ask ever more questions, requiring many extra packages of work, companies must adapt to the various agencies' styles and communication requirements, to minimize problems. Firms must think very carefully when requesting scientific advice!

## Contents

Introduction	Page 3
Critical success factors for communications with funding boards and organisations – perspectives from a Biotech Company	Page 4
Critical success factors for communications with funding boards and organisations – perspectives from a Venture Capital Organisation	Page 5
People are different; Objectives are shared? A look at the challenges of cultural differences	Page 7
Communication strategies for interacting with regulatory agencies	Page 8
Appendix – feedback from table exercises	Page 10

## Introduction

**Moira Thomson** (Fulcrum Pharma) and **Heidi Towers** (Medimmune)

The Pharma industry has become increasingly complex, where partners, mergers and acquisitions have become the normal way of working.

Effective communication can make the difference between success and failure, whether to investors, regulators/reimbursement committees, or between project teams and management boards within our own organisations.

Many tools are available to us, but we need to make sure that we are using them appropriately as well as increasing our understanding of cultural and timezone differences between the many players.

## **Critical success factors for communications with funding boards and organisations – perspectives from a Biotech Company**

**Phil Boyd, Syntaxin**

*NOTE: Phil's presentation slides are available also, in the PIPMG Members' Information Centre*

Regulators as we know are obliged to scrutinize companies data in detail, often on resubmissions where problems arise. On the other hand, potential investors and partners are not obliged to listen, may give us one chance only. They may make subjective judgements and focus on much more than data – business, people and science.

In seeking support from investors, companies must ensure communications and messages are consistent, from brief 'elevator pitch conversations' through formal presentations and due diligence.

Phil described how Syntaxin overcame communication challenges in attracting finance-oriented executives with its Botulinum Toxin novel mechanism – ensuring it was a simple, exciting message, with strong IP position and all company management team members aligned to the same messages. In some cases, natural fears about the word 'toxin' had to be allayed! Preparation, preparation is vital, trying to ask all the questions in advance – 'What do they want, Why should they invest, how to stimulate specific interest?'

As well as an upbeat, highly enthusiastic approach, more detailed business plans must build a realistic and coherent story – detailed plans of how the money will be used, the risks and returns. Every statement should be defensible. Rehearsal for staff is important, groups of whom may have to tell the science story when investors visit. The right attitude is a balance between confidence and arrogance! Remember that all relevant facts must be highlighted – misrepresentation will always come back to cause serious problems later.

In summary, the science must be good and the story must be clear and simple enough for the listener to understand. Everyone in the company should keep focussed, and speak with the same message!

## **Critical success factors for communications with funding boards and organisations – perspectives from a Venture Capital Organisation**

**Annegret de Baey, TVM Capital**

*NOTE: Annegret's presentation slides are available also, in the PIPMG Members' Information Centre*

Annegret described the evolution of TVM and some of the key lessons it has learned over the years of its growth, that can advise companies looking for investment.

Investors need to have people they can trust. Ideally a small, full-time, professional managing team, with business acumen not just an academically focused 'founder'.

The ideal investment opportunity is where there's a clear unmet medical need, with a possibility of dramatic effects on efficacy – not just an improvement in tolerability. Also with a defined market – with the potential product properly positioned within current standard of care. Any asset requires a strong IP position – not for example just a Use patent.

There needs to be a clear development path, with envisioned outcomes at defined milestones. Also a clear exit focus – where does the company want to be in 5, 10 years?

Presentations to VCs need to focus on the current therapy positioning, not just the overall market. Financial and time planning needs to be realistic. Tranches of money need to be aligned to value generating milestones.

'Focus, focus, focus' – one, solid asset is best to concentrate on, with a complete, committed team, confident but honest about predicted timelines, sales, etc. Try to get into the mindset of an investor. Also, build a good network of references – key opinion leader support matters.

## **Panel discussion**

The first two sessions were followed by a panel Q&A and discussion. Topics discussed were:

The need for absolute clarity on strategic direction – between the Project Team and the Governance bodies. Lots of time may need to be spent on this.

Relationship building is critical – decision bodies sometimes change / decisions often bounce all the way up to CEO level!

Agreeing how to work together, building respect – very important. Having key points of contact is critical – it's common to be working with a very long action list.

For grant-aided funding there are some important and special considerations:

- The WHO may already have a Target Profile
- They want a great deal of ethics reassurance
- Can you sell your product cheaply enough? A vital consideration
- Good communication across different cultures is vital

And a last point about VCs – remember that features of and responses from each one may be different – companies seeking funding may have to adapt tactics to each!

## People are different; Objectives are shared? A look at the challenges of cultural differences

**John Faulkes, PPMLD**

*NOTE: John's presentation slides are available also, in the PIPMG Members' Information Centre*

Individuals are different in terms of their personality; the profession they have become expert in separates them from others in some respects; the type of ethnic group people have grown up in, plus the type of organisation they have worked in for many years all have an effect on how they respond in certain situations. All of these differences sometimes make it hard for us to work together, yet creativity thrives on diversity – somehow we have to make it work!

Even in a single, co-located project team, managing styles may be different – for example, some constantly digress into the cut and thrust of new ideas, others press to stick to schedules and deliver on time. The team needs coordination to be able to 'fly in formation', and often a simple discussion of different 'work preferences', perhaps assisted by a tool such as Belbin team roles, the Colour Wheel, can resolve this quite quickly.

When we assemble multi-national teams, we may encounter more subtle problems. US and UK people may differ in terms of their directness. Yet both may appear similar to East Europeans along a different dimension, for example how well each will respond to a performance-related reward system. John explained Hofstede and Trompenaars 'dimensions' model of differences, including 'Rules vs. Relationship driven'; 'Group vs. Individual oriented'; 'Value of Achievements vs. Ascribed status', and how this informed us of things we should be careful to acknowledge when we are communicating, making decisions or being critical.

Another model, the 'Spiral Dynamics' work of Beck and Cowans, gives us insight into common problems faced in different approaches of two partner companies. For example, one may be entrepreneurial in nature, customer driven, where another is large, bureaucratic, driven by rules, processes and hierarchy.

In all multi-player organisations, where there are diverse partners and alliances, we can assess what are the significant differences and the risk to effective working. Nearly all differences of outlook and approach are resolved by feeding back, talking and building workable compromises!

**This talk was followed by the Workshop session – see the Appendix.**

## Communication strategies for interacting with regulatory agencies

**Leigh Shaw**, Gregory Fryer Associates

*NOTE: Leigh's presentation slides are available also, in the PIPMG Members' Information Centre*

Agencies will provide both approvals and advice. To get the best from interactions with them it is important to prepare for the differences between agencies and understand the lessons learned from many years of companies' working with them.

Advice points may be 'scientific' pre Phase 1, 2 or 3 – or 'pre submission' – before applying for MAA or Orphan status. In general, you have to tell agencies what you have done to date, what you propose to do – what proposed studies, or supply justification for no further studies. Utmost care should be taken in framing questions – only ask if you really want an answer. Advice given can generate for example, a different regime of studies for different territories.

For approvals, you need to balance supply of sufficient advice to get approval but not so much that they have to dig too far for relevant data. If they have a question, you must not 'fudge' it – it must be answered directly.

The form of communications between companies and agencies is changing. Much can be done globally in English, but bear in mind that letters from national agencies (as they are legal documents) may be in local language; Willingness to meet is changing – it has always been practice with the FDA but EU agencies are more willing to arrange meetings these days. The FDA increasingly encourages meeting by telecon. Regulators will typically ask questions of the company. You should take care to answer properly – but only provide what's been asked.

Agencies and sub departments of them may vary in their style. For example CTA vs MAA units in the EMEA. Remember also that the FDA are *decision makers* – the EMEA are *coordinators* of the expert committees.

Questions will often be asked at pre submission meetings, but these are also an opportunity to build relationships (for working together for 2-3 years!) and seek, for instance, potential rapporteurs. Orphan Drug hearings are somewhat different, multi-player meetings where decisions are made there and then. Presentations at these should be clear, to the point, avoiding argument.

**Panel Discussion:**

This session was followed by a Q&A and discussion. Topics discussed were:

*How do you know what is too much/too little information?*

Judge the authorities using your own common sense – if you can absorb something easily, they will.

*There is a danger of cherry picking?!*

Yes! And it is illegal to cover up ‘bad’ data

*How easy is it to get pre-IND meetings arranged?*

There are published timelines for the EMEA

With national agencies – it depends on their workload

*How easy is it to get information from the FDA?*

The quality of advice from the FDA is high – but you need to work at framing the right questions.

*Some experiences with national agencies:*

France: they were late (!); people weren’t introduced; but the advice was good

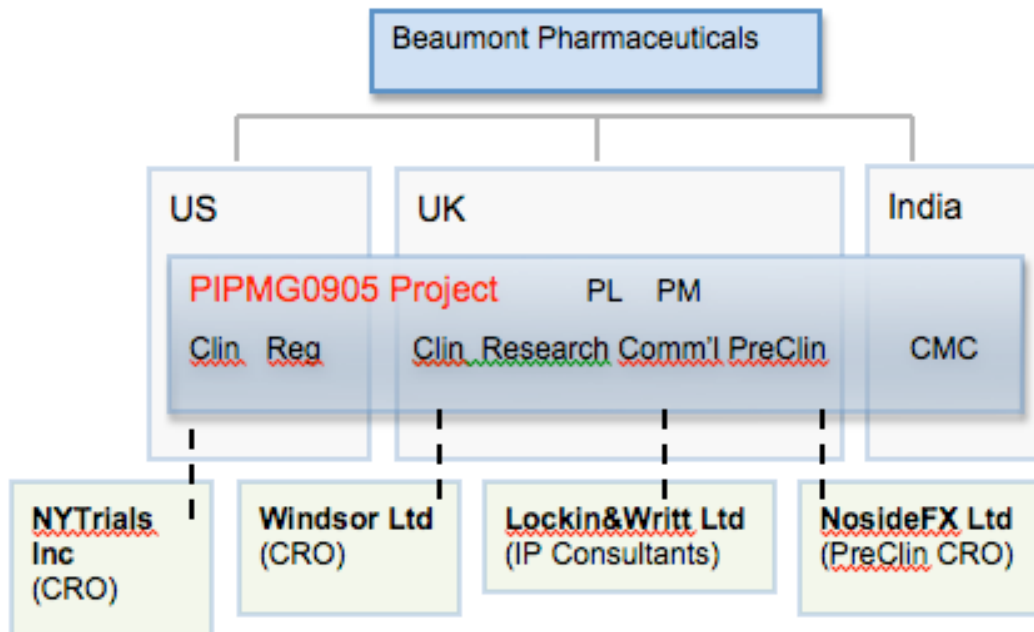
Sweden: they were neat, polite and well organised

*Pre-INDs – face to face vs. telecon:*

FDA are very happy with telecons, and generous with time at them.

The EMEA are going the same way, particularly for pre-submission meetings.

## Appendix: Feedback from Table Exercise



The above diagram was used to illustrate a case study: a medium sized pharma company with multi-national sites and strategic partners. Overlaid is one of the company's projects, and six different issues were posed for table teams to consider.

### Table 1 – What are the potential problems in setting up a regular regime of telecon meetings / what guidelines should be adopted?

Guidelines should be:

- Agenda and pre-reading should be sent out in advance
- The telecon system should be set up 5-10 mins before the start time
- One person only should speak at a time
- Roles should be defined:
  - Chair
  - Time keeper – should be aware of movements e.g. who will leave early
  - Minutes taker
- Telecon should start with an introduction to who is online
- Careful summaries should be made of decisions and actions (responsible persons and timelines)

If using web-based collaboration systems:

- Need to communicate guidelines for use
- Confidentiality – must be overtly addressed
- Need to clearly state what is the ‘official language’ – is it English or not?
- If CROs etc are to access (and they may need to) – need to establish protected folders etc and manage access properly
- Project folders need to be allocated to owners properly

**Table 2 – What are the potential problems in engaging in a ‘lessons learned’ review with a cross-cultural team / how to get the best out of these reviews?**

Potential problems with a cross-functional/cultural lessons learned review:

- Cultural differences
- Blame focus
- Communication differences
- People tired after travelling
- People afraid to speak
- Defensiveness/lack of trust

Benefits of cross-functional lessons learned review:

- Variety of ideas
- Global opportunities
- Increase of understanding
- Share best practice
- Issue resolution
- Build relationships and trust

Best practice for such a review:

- Get a strong, independent (perhaps external) facilitator!
- Make a clear action plan with ownership
- Add to or build a project charter
- Build ‘rules’ for meting behaviour
- Not a witch hunt!
- Anonymous feedback?
- Link process and behaviour
- Discuss both good and bad
- No blame
- Run the review after an icebreaker or team build, to build trust

**Table 3 – What issues should be addressed in a kick off/team build with a cross function/cultural team and what if any potential problems would you foresee?**

- Who will be represented at the meeting? Inclusive for all, including consultants?
- Planning the direction of subsequent meetings
- What do we expect to achieve from this meeting - networking only?
- Stakeholder analysis by the PM
- How formal will the kick-off meeting be?
- All stakeholders to attend the meeting? Should discuss guidelines for who should attend and what will be their responsibilities
- Pre-circulated guidelines for the meeting agenda/discussions (confidentiality issues?)
- Pre-circulated project information for the benefit of attendees (new project members?)
- Research director should briefly attend the meeting (not attend whole thing)

**Table 4 – Beaumont has a slow decision-making process / a very hands-on Research Director – what are the pitfalls and how to address them?**

Key pitfall #1: Continued slow decision-making – a varied level of detail, numerous loci of authority etc.

Recommendations

- Set expectations:
  - Information flow (verbal)
  - Information flow (written)
  - Level of detail, key content (risks, achievements, finance, etc)
- Evolve the system with experience
- PL to filter reporting?
- Cultural awareness training

Key pitfall #2: acceptance of new operating model

Recommendations:

- Explanation of operating model and reinforcement (ensure buy in)
- Ensure job roles in new structure are clearly defined and understood
- PL to lead the team and not the Research director!
- Team training for global and cross functional understanding (also including partners)

**Table 5 – Jenny Keen, the Project Leader needs to challenge the Research Director’s over-involvement, as well as improving team meeting focus – what advice could you give and how could her role be developed?**

- Jenny to negotiate for a global PL role and give up residual functional responsibilities
- Jenny to define team members – what functions are really needed as core team members
- Does the Research Director need to sit on all teams? Suggest he delegates.
- Need strong clinical input
- Look at options and scenario planning
- Jenny to do conflict management and negotiation skills training
- Identify the Research Director’s strengths and core skills and develop these

**Improving team meetings:**

- Make sure agendas/item timings are clarified in advance
- Send reading etc materials in advance
- Remove lengthy ‘for info’ updates
- Set expectations for meetings and required behaviours
- Established focussed sub team meetings that feed into the project team
- Strong meeting leadership
- Build a regime of core team / +ad hoc members, as agenda requires

**Table 6 – Changes are necessary to the project plan, which the PreClinical partner is not happy with; why isn't the relationship with them as good as it should be – and what can be done to improve it?**

Why is it not a good relationship?

- Beaumont seeing NoSideFX as a 'service provider'
- Lack of commitment to each other
- Buy in needed as to why changes need to happen
- A contract at 100% capacity at the start – not wise
- Beaumont CEO is very 'entrepreneurial' – NoSideFX may well be a 'bureaucratic' culture
- ....A typical real life example!!

What should have been done?

- Identifying risks – this should have come up!
- Thinking through properly what we want to do beforehand
- A 'partnership' rather than a 'service provider' relationship
- If we keep it to 'service provider'/'fee for service' – use them that way
- Pick a new supplier if they don't want to act in the way we decide?

What now?

- Get the two companies together
- Define a better way of working – clarify constraints
- Share the big picture / ask for NoSideFX's help