LIMS Deployment in an Assay Service Environment:
Improving Efficiency and Effectiveness through Information Management

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EXECUTIVE SUMMARY

In 2006 AstraZeneca (AZ) executed a strategy to centralise all biochemical screening activities within one of its Research Areas, into a single team. This team had the remit to deliver data faster and more consistently, whilst reducing the FTE's deployed against such activities. Keeping the team small, AZ hoped to facilitate more flexible use of resources, remaining agile enough to respond to changing business demands; however this centralised approach brought with it a fresh set of challenges, not least of which was information management. This review describes a successful LIMS implementation within AZ (who deployed a customised COTS solution in just four months). It outlines the steps taken over the initial system development life cycle and highlights the requirement for dedicated in-house resource (with intimate domain knowledge) coupled with experienced vendor personnel. It goes on to explore the requirement for continued evolution of the system and the challenges this posed.

Keywords: *AstraZeneca, Biochemical Screening, Centralisation, COTS, Efficiency, High Throughput Screening, Information Management, LIMS, Pharmaceutical, System Development Life Cycle*

ORGANIZATIONAL BACKGROUND

AstraZeneca is a major international healthcare business engaged in the research, development, manufacturing and marketing of prescription pharmaceuticals and is a supplier for healthcare services. In 2006 it had more than 12,000 Research and Development (R&D) employees spanning eight countries; the R&D function was divided into research areas (RA), each focusing on a particular disease setting and each operationally independent (Figure 1).

Typically pharmaceutical R&D begins with either a *High Throughput Screen* (HTS) or a more directed *Sub-Set Screen*, whereby the company's collection of chemical starting points is systematically tested against a biological target of interest. This process generally happens in a single high-cost activity and generates vast amounts of data which is then sifted in an attempt to derive an understanding of chemical structure versus biological activity, termed

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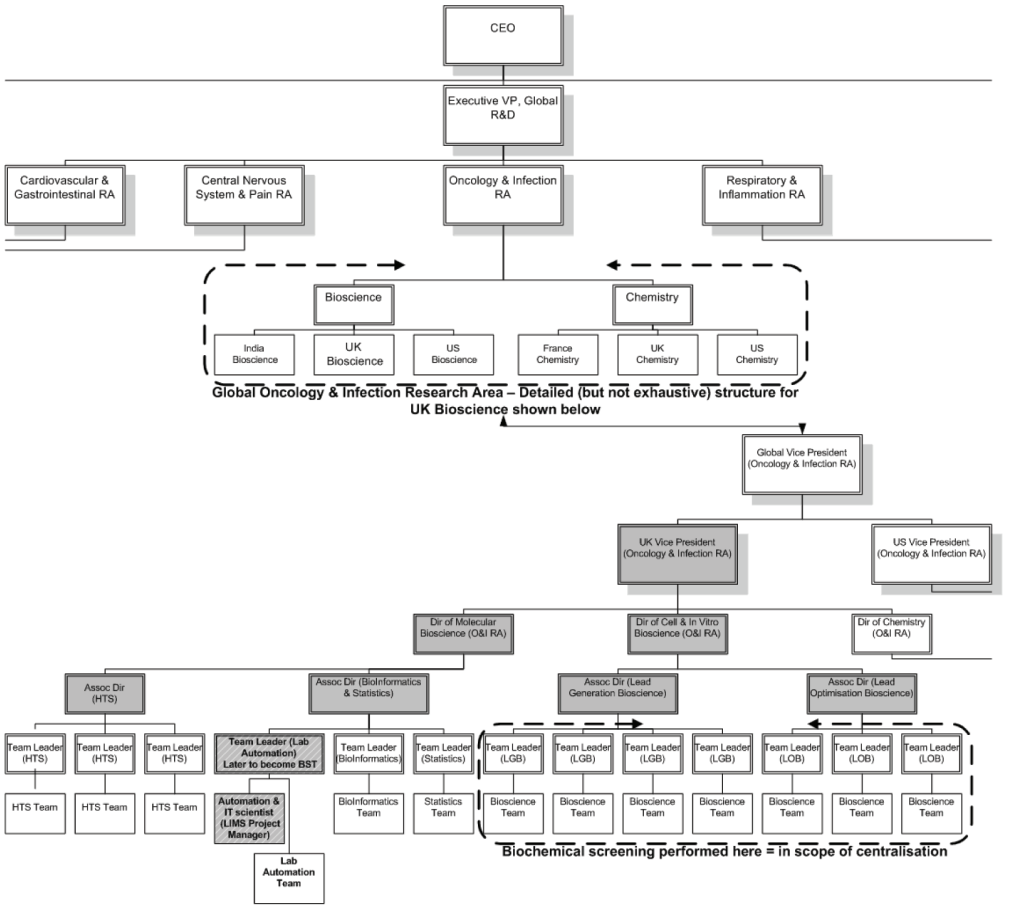
Figure 1. AZ Global R&D structure and Organisational chart for the 'Oncology & Infection, UK Bioscience section' (in 2006). The key players in formation and sanction of the business case for centralisation are highlighted (and can be seen in greater detail within Figure 2). Where the reporting line continues beyond the margin, a similar organisational structure to that shown should be assumed.



Structure-Activity Relationship (SAR). To add weight to SAR assumptions and to further enhance the pharmacological and physical properties of any 'hit' compounds identified, large amounts of chemistry resource is applied with the hope of turning these 'hit' molecules into appropriate 'leads.' With each round of chemistry, the new compounds are again tested against the biological target. This phase of SAR screening is iterative and will usually progress (with gradually decreasing throughput requirements) over a number of years until a given molecule's properties have been refined enough for it to become a 'Candidate Drug' and progress into the clinical phases of R&D.

SAR screening (sometimes referred to as 'Secondary Screening' or 'Efficacy Screening') within the pharmaceutical industry had traditionally been carried out within defined project teams, in many cases the same resource being utilised to deliver biochemical and cellular assay builds, along with the routine delivery of data through those assays. The constant drive for efficiency gains within Pharmaceutical R&D