

# DOE in Assay Development Trends 2009



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## Executive Summary

- This market report summarizes the results of HTStec's global Pharma, Biotech and Academic Research web-based benchmarking survey on the use of design of experiments (DOE) in assay development (AD) carried out in June 2009.
- The study was initiated by HTStec to meet the specific needs, interests and focus of the survey sponsors. The objectives were to examine: 1) how widely DOE approaches in AD are used; 2) what is the current level of understanding of DOE; 3) what views people hold about DOE and its benefits; 4) what success has been achieved; 5) which aspects of DOE are problematic; and 6) what restricts its wider implementation today. Equal emphasis was given to soliciting opinion from Pharma, Biotech and Academic Research segments, in both North America and Europe.
- The survey looked at the following aspects of DOE used in AD, as practiced to date (2009) and in some cases as predicted for the future (2011): whether AD is a bottleneck in respondent's organizations; the time taken to develop assays and the number of different combinations of assay conditions investigated using the traditional approach; number of assays developed per year and failure rates; what determines when AD is complete; primary applications areas of assays developed, and their use elsewhere in drug discovery; current level of knowledge and use of DOE; main benefits of DOE; reasons that have most prevented use of DOE; frequency of application of DOE to the development and optimization of assay conditions; whether DOE has resulted in any cost savings in AD; attempts at DOE using manual pipetting; which vendor's automated liquid handlers have been used, and which are most wanted for DOE; familiarity with commercial DOE software packages and approaches; the need to integrate DOE software packages using Microsoft Excel; levels of DOE design used; importance of drivers in adopting DOE; what is most needed to drive wider uptake and greater use of DOW; what a next-generation liquid handler designed for DOE must accommodate; target types most successfully investigated using DOE; current view on DOE adoption and expected future change in number of assays optimized using DOE over the next few years; current and future spending plans on DOE-related automated liquid handling; DOE software and training; DOE training status and preferred training type; and areas beyond AD where respondents plan to implement DOE.
- The survey questionnaire consisted of 28 multi-choice questions and 1 open-ended question. In addition, there were 7 questions related solely to survey demographics. The survey collected 68 responses (64 complete and 4 partially filled out) from 48 different organisations.
- Survey responses were geographically split: 53% North America, 44% Europe: and 3% Asia (excluding Japan).
- Survey respondents were mainly drawn from persons/groups actively engaged in the lead discovery, particularly AD, primary screening and/or profiling of assays. This included individuals/groups with experience of DOE that have investigated DOE's application in AD for HTS, and others involved in AD that have chosen not to use DOE or are considering using DOE in the future.
- Respondents came from 15 different Large Pharma; 13 University/Research Institute/Government Labs; 11 Medium-Small Pharma; 5 Academic Screening Centers and 4 Biotech Companies.
- Survey respondents represented: 20 Primary Screening Labs; 19 Labs with Multiple Drug Discovery Roles; 10 Assay Development Labs; 6 Other Labs; 4 Hits-To-Leads Labs; 3 Life Science Research Labs; 3 Basic Research Labs; 2 Secondary Screening Labs; and 1 Lead-To-Candidate Lab.
- Most survey respondents had a senior job role or position which was in descending order: 16 Section/Group Leader; 12 Senior Scientist/Researcher; 11 Director; 10 Research Scientist; 7 Principal Investigator; 5 Lab Manager; 2 Professor; 2 Department Head; 2 Other; and 1 Vice President.
- Survey results were expressed as an average of all survey respondents. In addition, where appropriate the data was reanalyzed after sub-division into the following 5 survey groups: 1) Large Pharma; 2) Medium/Small Pharma & All Biotech; 3) Univ. Res. Inst. & Gov't Lab; 4) Europe; and 5) North America.
- 43% of respondents reported AD was a problem in their organisations and gave feedback on their approach to compressing AD times without compromising on quality.
- The median AD time using the traditional approach (changing one setting at a time or sequential design) was 3-4 weeks for a biochemical assay and 1-2 months for a cell-based assay.
- A median of 5 assays were developed per lab per year, with a median failure rate of 5-10%.
- A median of 6-10 different combinations of assay conditions (factors) were explored using the traditional approach to AD for both biochemical and cell-based assays.

- Respondents ranked AD as complete when assay quality parameters and the desired assay window were achieved.
- The main purpose of the majority of assays developed was primary screening (HTS); most of these assays were subsequently used in secondary screening.
- The current level of knowledge of DOE of the majority of respondents was reasonably familiar.
- The main perceived benefit of DOE in AD was faster assay optimization.
- The reason that most prevents wider use or consideration of DOE was its too hard to implement.
- DOE is currently routinely applied in the development and optimisation of a median of <5% of all assays developed.
- The overall median cost savings that have resulted from using DOE in AD were 2 fold.
- Around 50% of respondents have attempted DOE using manual pipetting, with a median of <25% of their total DOE work done manually.
- Beckman Coulter automated liquid handlers were the vendor's platform most respondents have attempted DOE on, and the platform they most plan to use for future DOE.
- Familiarity with available commercial DOE software packages and approaches was generally low.
- Respondents using and/or familiar with DOE have for the most part: 1) found the need to integrate different DOE software packages using Microsoft Excel or a similar tool; 2) are concerned that commercial DOE software can lead to illogical biology recommendations; 3) used mainly fractional factorial and full factorial levels of design and made only limited use of surface area design.
- Thorough evaluation of assay variables was ranked the most important driver when considering adopting DOE.
- Better understanding/greater knowledge of DOE was rated most needed to drive wider uptake or greater use of DOE.
- Access to multiple reagents was rated most needed in a dispensing system to drive wider uptake and greater use of DOE.
- A future next-generation automated liquid handler designed for DOE must have compatibility with 384-well microplates or higher density; support a median total assay volume range of 5–10uL or lower volume; and support a median of at least 8 different assay reagents.
- DOE approaches to AD were viewed most applicable to biochemical assays, and less suited to cell-based assays.
- The target types most successfully investigated using DOE were biochemical assays (enzymes).
- DOE approaches need to be applicable to cell-based assays (GPCRs) to stimulate wider interest and/or encourage greater use in AD.
- The majority view of respondents on DOE adoption was to continue current usage unchanged.
- The median expected future change in the number of assays optimized using DOE approaches over the next few years (up to 2011) was a minor increase (0–25% rise).
- The median spending per survey respondent's lab on DOE today (2009) was none for automated liquid handling and none for DOE software and training. Estimated spending on DOE in the future (2011) is however predicted to increase significantly.
- A bottom-up model was developed around the respondent's use of DOE in AD and their spending on DOE to estimate the global Pharma-Biotech market for DOE-related automated liquid handling, and DOE software and training. The total market in 2009 for DOE-related automated liquid handling, and DOE software and training were estimated to be \$28M and \$4M respectively. The segmentation of these markets and CAGR estimates for 2011 was made.
- The current DOE training status of the majority of respondents was never been formally trained.
- The most useful DOE training was believed to be an integrated approach on-site.
- Optimising liquid handler dispensing settings was the area other than AD where the most respondents also plan to implement DOE.
- Feedback on unmet needs and general comments on the use of DOE in AD were documented.
- The full report provides the data, details of the breakdown of the responses for each question and the estimates for the future (2011). It also highlights several interesting divergent responses between the different survey groups.

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## General Information on HTStec and HTStec's Trends Market Reports

- HTStec Limited an independent market research consultancy founded in September 2003 whose focus is on assisting clients delivering novel enabling platform technologies (liquid handling, laboratory automation, detection instrumentation and assay reagent technologies) to drug discovery and the life sciences. Over the past 6 years HTStec has published 47 market reports mainly on drug discovery technologies and authored 27 review articles in Drug Discovery World.
- HTStec's Trends reports owe their origins to the need by developers and vendors of new enabling technologies in drug discovery to get up-to-date relevant market metrics on which to base informed business decisions.
- Typically focused on a specific market niche or segment, in many cases overlooked or frequently misunderstood by broader market studies.
- Investigations are mainly initiated in response to a sponsor's specific requests.
- HTStec's extensive experience of the market, both as a Pharma End-User and working for a major Life Science Tool Provider ensures the industry relevance of the market research collected.
- Based entirely on web-based feedback from potential customers typically drawn mainly from Pharma and Biotechs, although increasingly University and Research Institute labs are also being researched.
- Produced extremely rapidly and typically published within 3 weeks of starting the collection phase.
- Reports are short, concise and focused on giving readers the basic data, analyzed in several different ways.
- Limited to reporting the main findings alone, without exhaustive discussion on the relevance of the results.
- Market estimates are mainly based on bottom-up calculations and usually avoid attempts to forecast widely beyond the next 2-3 years. Full details on the derivation of market estimates are given so readers can apply their own factors and easily make alternative estimates if they prefer or know better.
- Owing to the sensitivity of some of the data collected, all reference to the origin of participating companies is removed, data is pooled to get an industry average and the anonymity of all respondents fully preserved and guaranteed.
- Unlike alternatives HTStec's Market Surveys and Report are aimed at giving readers, information they want and can rely on, not information they don't need, cannot easily discern or is of dubious authenticity.
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