

Cell-Based Assays For Biologics Trends 2011



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Executive Summary

- This market report summarizes the results of HTStec's industry-wide global web-based benchmarking survey on cell-based assays for biologics carried out in July 2011.
- The study was initiated by HTStec as part of its ongoing tracking of emerging life science marketplaces. The questionnaire was compiled to meet the needs and interests of the cellular assay reagent vendor community. The main objectives were to comprehensively document current end user opinions, practices and preferences in the development of bioassays for large molecule (biologics) applications in drug discovery, and to understand future requirements.
- The survey looked at the following aspects of cell-based assays for biologics as practiced today (2011) and in some cases as predicted for the future (2013): proportion of respondent's drug discovery efforts directed towards large molecules; disease areas being targeted with biologic drugs; use of binding assays versus cell-based assays; the most important drivers for using cell-based assays for biologics applications; biggest limitations faced in developing cell-based assays for biologics; components of most interest in biologics cell-based assay workflow; types of biological matrices of most interest for developing into a cell-based assay; assay formats/readouts of most interest in using for cell-based assays for biologics; detection technologies most frequently used when performing cell-based assays for biologics; cell-based bioassay types performed in the evaluation of biologics; interest in accessing bioassay-qualified reagents to address cytotoxicity/viability testing; current use of reporter-based assays for biologics assay development; relevance of a reporter-based assay that demonstrates mechanism of action; interest in multiplexed bioassays; interest in performing bioassays in 384-well plates; feature that is most attractive for biologics lot release using cell-based assays; requirement to purchase specific lots of a bioassay kit or component; maximum timeline requirements for lot availability; requirement to purchase bioassay reagents manufactured under GMP conditions; sources of bioassays used for biologics; use of frozen, ready-to-use cells in bioassays; metrics associated with the use of cell-based assays for biologics; critical performance parameters in cell-based assays for biologics; annual budget for cell-based assays in biologics and its component breakdown; price expectations per well for cell-based assays in biologics; most familiar commercial supplier of products supporting cell-based assays for biologics; and unmet needs in the area of cell-based assays for biologics.
- The main questionnaire consisted of 28 multi-choice questions and 2 open-ended questions. In addition, there were 5 questions related solely to survey demographics.
- The survey collected 101 validated responses, of these 72% provided comprehensive input.
- Survey responses were geographically split: 49% North America; 33% Europe; 8% Asia (excluding Japan); 8% Rest of World and 2% Japan.
- Survey respondents were drawn from persons or groups interested in and/or investigating cell-based assays for biologics applications in drug discovery.
- Respondents came from 35 University/Research Institute/Government Lab (Not-for-Profit) Facilities; 26 Biotech; 13 Medium-Small Pharma; 12 Large Pharma; 8 Contract Research Organizations; 4 Others; and 3 Academic Screening Centers.
- Most survey respondents had a senior job role or position which was in descending order: 22 research scientists; 15 senior scientists/researchers; 12 directors; 10 other roles; 10 principal investigators; 10 section/group leaders; 6 professors/assistant professors; 5 lab managers; 4 department heads; 4 post-docs; and 3 vice presidents.
- Respondents represented the following labs: 23 biologics R&D; 23 cell-based assay R&D; 19 basic research; 13 other; 10 cell-based screening; 4 therapeutic antibody R&D; 3 reagent/target generation for screening; 2 contract R&D for biologics; 1 biologics production; 1 vaccines production; 1 therapeutic antibody production; and 1 cell-line development.
- Survey results were expressed as an average of all survey respondents. In addition, where appropriate the data was fully reanalyzed after sub-division into the following 6 survey groups: 1) Pharma; 2) Biotech; 3) Academic Research; 4) Biologics Focus; 5) Europe; and 6) North America.
- Most respondents had a high level of interest in developing/using cell-based assays for biologics.
- A median of 30% of respondents drug discovery efforts today (2011) were directed exclusively towards biologics (large molecules).
- The majority of respondents were investigating/targeting biologics drugs in the oncology/cancer disease area.

- Respondent's feedback on the most important future targets for biologic drugs were documented.
- The current (2011) usage of different assays types for biologic screening was 45% cell-based assays, 37% binding assays and 18% other assay types.
- Functional, mechanism of action-based was the most important driver for cell-based assays for biologics.
- Maintaining adequate data quality, assay robustness & reducing variability was rated as the biggest limitation in cell-based assays for biologics.
- Reduced assay variability was ranked as the component of greatest interest in their biologics cell-based assay workflow.
- Proteins were the biological matrix respondents have the greatest interest in developing into cell-based assays.
- Cytotoxicity was ranked as the assay format/readout of greatest interest for cell-based assays for biologics.
- Fluorescence intensity was rated as the most heavily used detection technology when performing cell-based assays for biologics.
- ADCC (antibody-dependent cell-mediated cytotoxicity) was the bioassay type most performed for the evaluation of biologics.
- The majority of respondents were interested in accessing bioassay qualified reagents to address cytotoxicity/viability testing of biologic candidates in ADC assays.
- The majority of respondents currently make use of reporter-based assays for biologics assay development.
- Most respondents believe that a reporter-based assay that demonstrates mechanism of action in ADCC assays will be highly relevant.
- The majority of respondents were interested in multiplexed assays for biologics.
- The majority of respondents were interested in performing biologics bioassays in 384-well plates.
- The feature that is most attractive to respondents for biologics lot release, using cell-based assays was ease of use.
- The majority of respondents do not purchase reagents or kits with specified lot numbers.
- The most desired timeline for guaranteed availability of a kit or component lot was up to 6 months.
- The majority of respondents have no requirement to purchase components or kits for bioassays manufactured under GMP conditions.
- The majority of bioassays for biologics were developed/sourced in house.
- The median current (2011) metrics for the use of cell-based assays for biologics were: 8 unique samples per plate; 6 dilutions per unique sample; 3 replicates per sample; 6 control wells per plate; with 16–20 96-well plates processed per month.
- Low CV (i.e. minimal variability) was ranked as the most critical performance parameter in cell-based assays for biologics.
- The median budget allocated by respondents for spending on cell-based assays for biologics today (2011) was \$50K–\$100K. The biggest proportion of this budget was allocated to bulk reagents/assay components.
- A bottom-up model was developed around the respondent's spending on cell-based assays for biologics to calculate the global market, in 2011 this was estimated be around \$183M. Segmentation and CAGR estimates are given in the full report.
- The most familiar commercial suppliers of products supporting cell-based assays for biologics were Life Technologies, Promega, Sigma Aldrich and BD Biosciences. Together these suppliers they were estimated to have around 50% market share.
- The median price paid per well for cell-based assays for biologics were: \$0.75–\$1.00 current average cost per well; \$0.25–\$0.50 desired/target cost per well; and \$1.00–\$1.50 maximum cost per well.
- A few unmet needs in the area of cell-based assays for biologics were highlighted.
- The full report provides the data, details of the breakdown of the responses for each question, its segmentation and the estimates for the future (2013). It also highlights a few interesting differences between the 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. Over the past 8 years HTStec has published more than 50 market reports on drug discovery technologies and authored over 30 review articles in Drug Discovery World (at least one article per issue).
 - 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 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.
 - 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.
 - Critically HTStec's Trends reports have generated much interest and acclaim amongst survey respondents, to whom they are made available free of charge (subject to acceptance of HTStec's copyright terms) so they can benchmark their internal processes.
 - 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.
 - HTStec aims to be the premier global provider of highly focused market research on enabling technologies in drug discovery.
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