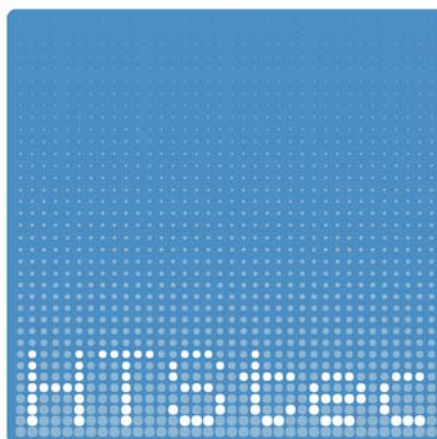


Compound Management Trends 2004



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Executive Summary (1)

- This market report summarizes the results of a global benchmarking study on pharmaceutical compound management (CM). The report was based on the results of web-based survey of Pharma and Biotech CM groups. The objective of the study was to comprehensively document current practices, issues and future trends in CM, with a particular focus on compound quality control and just-in-time (JIT) compound delivery.
- The survey collected 70 responses (63 complete and 7 partially filled out) from 50 different Pharma & Biotech companies and 2 University/Research Institutes.
- Responses from were split geographically 44% North America and 56% Europe.
- Survey respondents were drawn from 32 Small-Medium Pharma/Biotechs, 31 Large Pharma, 2 Agrochemical Companies, 2 Contract Service Organisations, 2 University/Research Institutes and 1 Cosmetic Company.
- Respondents were either directly responsible for or directly involved in compound management within their company; or were closely involved in the preparation of assay ready plates from stocks provided by compound management. They represented 40 compound management groups; 20 screening groups; 3 corporate research management group; and 7 other groups.
- All data was presented and analyzed as the average response of All Survey Respondents. In addition, the data was fully reanalyzed after sub-division into the following 4 survey groups: 1) Large Pharma; 2) Small-Medium Pharma/Biotech; 3) Purchased Commercial Stores; and 4) Use of In House Alternatives.
- The mean size of a compound library today (2005) was 0.81 million compounds, this is expect to grow 1.42 million by 2008.
- Nearly one third of companies surveyed still use an ad hoc arrangement of lab freezers as the main component of their CM store.
- 60% of respondents had purchased a commercial CM store. REMP was the most popular commercial provider of the main component of their CM stores.
- Of the CM stores surveyed 68% represented a main (central) store, 27% a local site store and 5% a satellite lab store.
- Of the CM stores surveyed most used microplates and microtubes in part of the same facility;
- 89% of all liquid stocks today are in 100% DMSO (assumed starting concentration).
- The most common storage volume today is 0.1–0.5ml, this is also expected to be the case in 2008.
- 96-well format remains the most popular compound storage format/density today. It is expected that regular volume 384-well will be the most used compound storage format/density by 2008.
- 384-well (regular volume) format is the most popular assay density today and is expected to remain so in 2008.
- The majority of assay ready plates are prepared today by the end user (i.e. HTS groups).
- Opinions on sampling from storage tubes were equally divided between those who prefer piercable septa versus those that prefer a capping/decapping strategy, with a growing number of respondents who prefer individually sealed, single use tubes.
- Water uptake (ingress) during reformatting was seen as the main reason for sample integrity being compromised in DMSO liquid stores.

Executive Summary (2)

- Of the QC measures respondents have applied to their entire library, regular QC of liquid handling equipment and volume measurement (remaining) have been implemented to the greatest extent.
- Of the QC measures respondents have applied to pre-selected and/or to randomly selected compounds integrity/structural validation and purity have been implemented to the greatest extent.
- Of the QC measures respondents are considering applying in the future greatest interest was shown in the hydration status of the solvent, followed by solubility (precipitate) detection.
- Technologies being considered for real time high throughput sample QC analysis include LCMS with various multichannel detection systems, particularly ELSD and CLND applied. Labcyte's Echo 550 was viewed as the most promising new tool for fast water content analysis, particularly when it is made compatible with mini-tubes.
- The mean cherry-picking capacity achieved for initial hit validation and IC50's was 701 picks/hour and for smart screening of smaller iterative sets was 900 picks/hour. The mean cherry-picking capacity desired for initial hit validation and IC50 was 1148 picks/hour and for smart screening of smaller iterative sets was 2213 picks/hour.
- Respondents' feedback on 1) how they quantify the output/performance/added value of their CM area and 2) on compound stewardship/savings and their strategy to replace legacy stocks or to acquire new stocks are extensively documented.
- The most prevalent current manufacturing practice for liquid stocks in the CM area is to a stock level.
- The CM strategy most appealing to respondents was the single use of assay ready plates with a small μL volume (for intermediate dilution before assay).
- The CM strategy that best describes all respondents current situation is split equally between Assay Ready Plate Storage and JIT Compound Delivery.
- A seal and pierce, freeze and thaw strategy was seen as the most preferable CM option.
- Speed of accessibility and availability was perceived to be more important than compound usage, efficiency and savings.
- Individual tubes selectable/picked from a store was rated to be of greater flexibility than individual well access.
- The use of a controlled environment in the compound storage area was considered the best approach to deal with compound precipitation.
- A cherry-picking requirement was ranked as the most important factor in justifying a CM store.
- Reliability and sample integrity were ranked highest when choosing a CM store.
- The main issue facing CM groups today was sample integrity, with retrieval rated the biggest bottleneck.
- Respondents' feedback on biggest challenges/changes to existing requirements they individually expect to encounter in the next few years are extensively documented.
- Some marked differences in respondents CM facility, compound quality control, just-in-time (JIT) compound delivery, CM store preferences, issues and bottlenecks were identified between the responses of the different survey groups.

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HTStec's TRENDS MARKET SURVEYS & REPORTS – Focus, Format and Content

- HTStec's 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 only initiated in response to a sponsors 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.
- 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.
- Full details on the derivation of market estimates are given so readers can apply their own factors and easily make alternative estimates.
- 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, 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.
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