日本 ISPE 創立記念大会プログラム

２００２年６月１２日・１３日

江戸川区総合区民ホール

６月１２日[9:30 開場]

創立総会[10:00-11:00]

基調講演[11: 30-12:30]米国 FDA 派遣講師

GMP COMPLIANCE/FDA UPDATE AND RECENT ICH ACCOMPLISMENTS

―FDA の規制・GMP の最新動向と ICH の進捗―

特別講演[13:30-18:00]ISPE 国際本部派遣講師

1．THE PHARMACEUTICAL MARKET－A Global Perspective

―医薬品市場の世界展望―

2．TECHNOLOGY TRANSFER － Discovery to Market：技術移管-研究から上市

3．21CFR PART 11（GAMP）：電子記録・電子署名－欧米の現状と FDA の考え方

4．MANUFACTURING PERFORMANCE：医薬品製造の国際戦略

創立記念交流会[18:15-20:30]

６月１３日[9:30-16:30]

ワークショップ：日米欧専門家によるパネルディスカッション

1. 欧米の規制とGMP の最新動向
2. 電子記録・電子署名21CFR Part 11－現状と今後の展開
3. 生産効率改善のためのベンチマーク評価
4. 技術移管ガイドライン－コンセプトから実用化へ

（製剤機械技術研究会国際委員会テクノロジートランスファーガイドラインワーキンググループとの共同企画）

第 1日目　6月 12日（水）

第 1部 :ISPE 日本地域本部創立総会（大ホール）

10:00― 11 :00 総合進行　長田伸一 ISPE日本地域本部理事／事務局長　（日揮 営業本部　部長）

1．会長挨拶……平地富安　ISPE日本地域本部会長（武州製薬　社長）

2．経過報告……長田伸一　理事／組織委員長（日揮　営業本部　部長）

3．会則報告……平地富安　会長（武州製薬　社長）

4．役員報告……栄木憲和　副会長（バイエル薬品　取締役／滋賀工場マネージャー）

5．予算報告……京極博　理事／財務担当（千代田化工建設　本部長補佐）

6．委員会活動報告

＊ 教育委員会……　委員長代理　宮嶋勝春　理事（テルモ 主任研究員）

＊ レギュラトリー関係委員会……委員長 山本恵司　理事（千葉大学　薬学部　学部長 ）

＊ ベンダー委員会……委員長 栄木憲和　副会長（バイエル薬品　取締役／滋賀工場マネージャー）

＊ DISCUSSION FORUM 委員会…委員長 高嶋武志　理事（パウレック　代表取締役社長）

7．ワークショップ関連説明……　高嶋武志　理事（パウレック　代表取締役社長）

8．閉会

第 2部 :創立記念大会講演会（大ホール）

11:15―大会実行委員長挨拶　山本恵司　理事／レギュラトリー委員長　（千葉大学　薬学部　学部長）

11:20―11:30 祝辞……ISPE 国際本部　最高運営責任者　Robert P. Best

１１：３０－１２：３０

基調講演……座長　山本恵司　理事／大会実行委員長

GMP COMPLIANCE/ FDA UPDATE AND RECENT ICH ACCOMPLISHMENTS－FDA の規制・GMP の最新動向とICH の進捗

スピーカー　Charles P. Hoiberg PhD (Director, FDA/CDER)

本講演では、FDAにおける最新の動向について紹介するとともに、最近のICHをめぐる成果およびその国際的なハーモナイゼーションへの影響について述べる。また、海外査察の増加に対応する新たな品質システムアプローチについても紹介する。

This presentation will provide information on the latest developments in the FDA, as well as discuss recent ICH accomplishments and the impact on harmonization. The new quality system approach to inspections will also be discussed along with the increase in overseas inspections.

12:30―13:30 昼食（イベントホール）

１３：３０－１４：３０

特別講演　１．…… 座長　栄木憲和　副会長（バイエル薬品　取締役／滋賀工場マネージャー）

THE PHARMACEUTICAL MARKET - A GLOBAL PERSPECTIVE― 医薬品市場の世界展望

スピーカー.Carl J. Fearn (Sales Director, IMS Health)

IMS のデータをもとに最近の世界の製薬企業および市場動向などについて説明するとともに、今後5年間における主要な市場と治療領域についての売り上げ予測について言及する。さらに近い将来上市が予定されている大型製品に焦点をあてながら最近の研究開発動向を紹介する。

This presentation, utilizing in -depth IMS data and insight, will provide a review of recent market trends around the world with an analysis of leading corporations, markets and products. Sales forecasts for the next five years provided by major markets and by leading therapy areas will be covered. Also included will be a review of recent developments of pharmaceutical R&D pipelines with an emphasis on potential blockbuster drugs close to launch.

１４：３０－１５：３０

特別講演　２．……座長　服部宗孝　理事（山之内製薬　製剤技術研究所　部長）

TECHNOLOGY TRANSFER - Discovery to Market －技術移管に関わる FDA 査察の留意点

スピーカーJoseph X. Phillips ISPE国際本部理事（Vice President, Quintiles Consulting）

技術移管プログラムのベースとなる開発計画及び開発データの文書化に関する全体概念について紹介する。高度な開発計画及び文書化は実生産バッチのプロセス・バリデーションを成功させるのに必要であり、且つベースとなるものである。FDAが期待するところの「開発」、「技術移管」及び「バリデーション」は科学的根拠に基づいていること、又開発初期の製品と市場にでる製品の間で科学的関連性が確立されていることについて述べます。

This presentation describes the overall concepts involved in the planning and documenting of good development data that becomes the basis for a sound technology transfer program. Advanced planning and documentation is necessary for successful validation of the process for full-scale batches. The presentation will describe FDA's expectation that the development, technology transfer and validation be based on good science and that a scientific link must be established between the original product developed and the product to be marketed.

１５：３０－１６：００　コーヒーブレイク

１６：００－１７：００

特別講演　３．.....座長　三宅康夫 理事／実行委員長代行（内藤くすり記念館　館長：エーザイ）

21CFR PART 11 (GAMP) －電子記録・電子署名；欧米の現状と FDA の考え方

スピーカーTony Margetts, International Project Manager（AstraZeneca）

ISPEが刊行している21CFR Part 11関連の出版物を紹介します。ひとつ電子記録および電子承認に関するコンプライアンスとお奨めのプラクテスについてまとめたものでISPEとPDAがシリーズの第2巻として共同刊行したものです。更にISPEが最近刊行したばかりの自動化システムのバリデーションに関するGAMP4 Guideを話題にします。
Good Automated Manufacturing Practice (GAMP) guidanceでは現行のあらゆるヘルスケア関連の法規制を満足するバリデートされた自動化システムを作り上げることを目標としました。この新ガイドは旧版を大幅に改訂しておりバイオテクノロジーと医療用器具分野にも広げました。

This presentation describes the ISPE publication on 21 CFR Part 11. This is the second volume in a series on compliance and good practice for electronic records and signatures published jointly by ISPE and PDA.
The presentation also discusses the ISPE publication GAMP 4 Guide to the Validation of Automated Systems. Good Automated Manufacturing Practice (GAMP) guidance aims to achieve validated and compliant automated systems meeting all current healthcare regulatory expectations. The new GAMP Guide is a significant advance on previous versions and has been widened to include biotechnology and medical devices. Aspects of the Guide will be introduced.

１７：００－１８：００

特別講演　４．.....座長　林昭雄　理事　（石川島播磨重工　プロセスプラント統括部長）

MANUFACTURING PERFORMANCE－医薬品製造の国際戦略

スピーカーRichard Davis（元 Bristol Myers Squibb）

今日の医薬業界では品質は競争力上重要な要素である。この講演では品質管理組織の役割及びビジネスにおけるその価値について議論する。品質が確実に製品に作りこまれる技法について述べます。

In today’s industry quality is a competitive advantage. This presentation will discuss the role of the quality organization and its value to the business. Techniques will be described to assure that quality is built into the product.

第3部 :創立記念交流会（イベントホール）

18:15−20:30 総合司会　京極博　理事　財務担当

挨拶　平地富安　ISPE日本地域本部会長

乾杯　Robert P. Best ISPE最高運営責任者

第２日目　６月１３日（木）

ワークショップ（イベントホール）

09:30–12:00　**ワークショップ－１　(会場 :福寿)**

欧米の規制とGMPの最新動向

Co-Chair :長谷川正樹　Discussion Forum　リーダー　(三重県科学技術センター長)
　　Joseph X. Phillips　国際本部理事　(Vice President, Quintiles Consulting)
Panelist：石井勇司　静岡県庁　健康福祉部　薬事審査室　主任)
　　西岡和幸　参天製薬　品質保証 ･環境監査本部長)
　　Joseph X. Phillips　国際本部理事　(Vice President, Quintiles Consulting)

09:30–12:00　**ワークショップ－２　(会場 :桃源)**

電子記録 ･電子署名　21CFR Part 11

Co-Chair :荻原健一　Discussion Forumリーダー　横河電機　産業ソリューション事業部　薬品技術部長)
　　Tony Margetts　(International Project Manager, AstraZeneca)
Panelist：荻原健一　Discussion Forumリーダー　横河電機　産業ソリューション事業部　薬品技術部長)
　　奥川隆政（ファイザー製薬　品質保証部　主任研究員)
　　Tony Margetts　(International Project Manager, AstraZeneca)
　　早川禎宏　島津製作所　分析計測事業部　LCビジネスユニット主任)

12:00–13:00　昼食　（ 会場 ： 福寿　／ 桃源 ）

13:00–16:00　**ワークショップ－３　(会場 :福寿)**

生産効率改善のためのベンチマーク評価

Co-Chair :栄木憲和　日本ISPE副会長 (バイエル薬品　取締役／滋賀工場マネージャー)
　　Richard Davis :元Bristol Myers Squibb
Panelist :古田弘信　第一製薬　人事部人事グループ　課長)
　　Richard Davis　(元Bristol Myers Squibb)
　　北室圭司　(バイエル薬品　滋賀工場　企画管理)

13:00–16:30　**ワークショップ－４　(会場 :桃源)**

製剤機械技術研究会国際委員会テクノロジートランスファーWGとの共同企画

技術移管ガイドライン－コンセプトから実用化へ－

Co-Chair :宮嶋勝春　理事　(テルモ　研究開発センター　主任研究員)
　　Joseph X. Phillips　国際本部理事　(Vice President, Quintiles Consulting)

Panelist:　冨田貞良　(三菱化学ビーシーエル　顧問)
　　福原克哉　(日本たばこ産業　生産技術研究所　GL)
　　北沢義夫　日本製薬工業協会　(企画部長)
　　Joseph X. Phillips　国際本部理事　(Vice President, Quintiles Consulting)

米国 FDA 及び ISPE 国際本部派遣講師の紹介

Richard J. Davis was most recently with Bristol-Myers Squibb as a Consultant. Prior to this he was Senior Vice President for Quality and Compliance at DuPont Pharmaceuticals. For thirty-three years, Davis was also regional food and drug director for the FDA.

Carl Fearn is Sales Director, Global Services for IMS Health. For the last nine years he has been involved with pharmaceutical and active ingredients markets. He joined the Global Services Group of IMS Health in 1995 as the marketing manager of Chemical Division. He also was head of the Chemical Division, head of the Business Development Group, and General Manager, Japanese Sales Group, of Global Services. His early career was with the Japanese Trading House, Mitsui & Co. Ltd., as a trader in petrochemicals and organic chemicals. This was followed by a move to MTM plc, the UK fine chemicals company. He was based in the Hong Kong and USA during most of his seven years with MTM. On leaving MTM he was the European Commercial Manager for MTM Pharmachemicals division. Fearn is a regular speaker for IMS HEALTH at industry conferences around the world. He holds an honours degree in Chemistry from UCL of the University of London.

Ashley Hankinson graduated with joint honours in analytical chemistry and toxicology before undertaking postgraduate research in psychopharmacology. Subsequent to his academic studies, Ashley held both scientific and management positions within several multi-national pharmaceutical companies, both in North America and in Europe, prior to becoming head of scientific consultancy for a large consultancy organization. As part of this position Ashley was responsible for operations both in Europe, the United States and South East Asia. After seven years, he recently joined the merged Janssen Research Foundation and R. W. Johnson Pharmaceutical Research Institute, a Johnson & Johnson Company, as their Global Director of Quality and Compliance Management. Hankinson's technical expertise is within regulatory compliance and in particular validation. He is a compliance specialist, both in GLP and CGMP environments and in particular within the areas of cleaning/decontamination and process validation. Hankinson is a member of ISPE, PDA, Nordic R3, European GAMP Suppliers Forum and a lead member of the GAMP Americas Laboratory Special Interests Group. He regularly presents at international meetings for these organizations.

Charles Hoiberg, PhD, is currently Director of the Division of New Drug Chemistry I, Office of Pharmaceutical Sciences, Center for Drug Evaluation and Research (CDER), FDA. He worked over eight years at a pharmaceutical company before joining the FDA. His previous positions with FDA include: review chemist, supervisory chemist in the Division of Surgical Dental Drug Products and in the Division of Oncology and Pulmonary drug Products. Hoiberg received his BS degree in Chemistry from the College of William and Mary and his PhD in Biochemistry from Pennsylvania State University.

Tony Margetts is an International Project Manager for AstraZeneca, and has worked 15 years in the Pharmaceutical Industry. His wide-ranging responsibilities include Computer System Compliance and Validation within AstraZeneca as well as computer systems covering MRPII, LIMS, EBRS, LIMS, manufacturing equipment, and laboratory equipment. He was formerly International Computer Systems Validation Manager for Zeneca Pharmaceuticals. He was founder member of the GAMP Forum, and was Chairman of the sub-committee that was formed to produce the first GAMP Guide. He is chairman of the GAMP Special Interest Group on 21 CFR Part 11 compliance, and was also Chairman of the GAMP4 Editorial Review Board. Margetts has been actively involved in validation planning, supplier audits, and managing FDA inspections over many years. Recently he has worked on the new GAMP document on ER-ES.

Joseph X. Phillips joined Quintiles Consulting on February 1, 2001 as Vice President of Pharmaceutical Operations following a 44-year career with the Food & Drug Administration. As Vice President for Pharmaceutical Operations with Quintiles, Phillips is providing executive leadership and direction to help position Quintiles Consulting as the world leader in pharmaceutical consulting services. In this capacity, Phillips leads a team of specialists with expertise in regulatory matters that can be of significant value to Quintiles' pharmaceutical clients. He spent his FDA years working in Philadelphia as an investigator, supervisory investigator, deputy director of investigations, assistant to the regional F&D director, and most recently as deputy director regional food & drug director of the central region. He has been heavily involved in planning and managing pharmaceutical programs throughout his career, including the Pre-Approval Inspection Program and SUPAC (Scale Up/Post Approval Change) field operations. He has been executive secretary of the Agency's Field Drug Committee for over 10 years. He has been an active member of the International Laboratory Forum on Counterfeit Medicines since its inception. Phillips is a life member of the ISPE and has been an active participant on behalf of the FDA in the development of their series of Baseline Engineering Guides, and the SUPAC Equipment Addendum. He has received the ISPE's highest award, The Richard B. Purdy Distinguished Achievement Award in 1999. He has received ISPE recognition for Outstanding Service to the Guide Steering Committee in 1998 and the ISPE Certificate of Appreciation for Outstanding Contributions to the development of the Bulk Pharmaceutical Guide in 1993. He was recognized by the NJ Association for Science & Technology on March 18, 1999. Phillips has been the recipient of three Vice Presidential Hammer Awards for reinvention efforts on SUPAC (collaborative work with CDER and ISPE) and for International Collaborative Efforts dealing with API Anti-Counterfeiting/Sourcing Efforts.