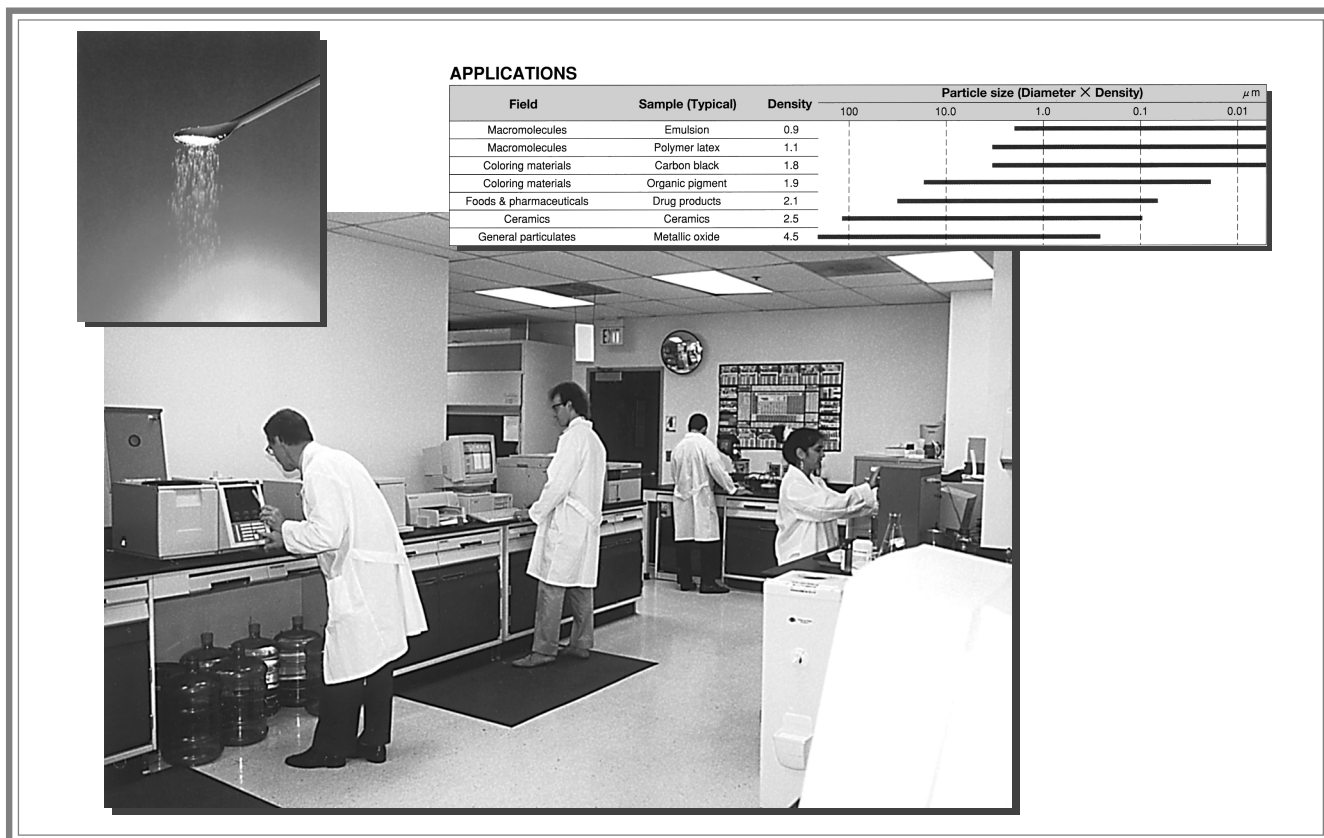


The Role of the Applications Laboratory in Particle Size Analysis

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要旨

ホリバ・インスツルメンツ社(HII)にアプリケーション・ラボが設置されてから16年が経過した。この間、ラボの役割は 粒子径計測装置の販売前支援から 特殊な粒子計測方法の開発へと発展してきた。本稿では、その発展過程を簡単に紹介し、製品販売や開発そしてお客様にいかにか満足していただくかについて詳しく述べる。粒子径の測定装置は、年々、高度にまた複雑化されており、ラボ担当者は、市場ニーズに合わせて技術の向上をはかっている。FDAの新たな規格への対応、ISO-9001の取得・維持、さらにはASTMが主催する“相互試験”などにも積極的に参加している。これらの活動を通して、このアプリケーション・ラボがホリバの世界中のお客様に付加価値をお届けしている。

Abstract

In the sixteen years since the applications laboratory was established at Horiba Instruments, Inc. The role of the laboratory has evolved from providing pre-sales support to developing sophisticated customized solutions to unique particle size analysis problems. This article briefly describes the history of the applications laboratory and details the roles it has played in product sales, support, development, and achieving customer satisfaction. As particle size analysis instruments have become more sophisticated and complex, the laboratory staff has had to learn new skills and adapt to changes in the needs of the marketplace. The impact of new FDA regulations on instrument performance and the requirements of achieving and retaining ISO-9001 registration are described. The attention to accuracy and reliability has led to an ongoing participation in ASTM-sponsored “cross-check” testing to validate the performance of Horiba’s instruments. The article concludes with an assessment of how the applications laboratory provides value to Horiba’s worldwide customers.

<Early Laboratory Work>

At Horiba Instruments, Inc. we established our applications laboratory in 1984 to support our customers. The role was originally confined to validating the performance of Horiba's products by measuring customer-provided samples before the customer placed an order for products. The concept of the applications laboratory was developed by Dr. Robert Gafford to assure that the equipment was properly installed at the customer's facility by Horiba personnel. Since this time our facility has grown rapidly, as has the number of people performing this function. The original mission is still critical, but it has grown in many different directions.

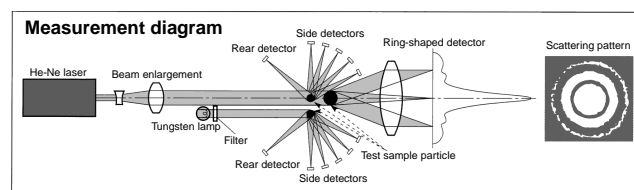
The applications laboratory was originally founded to aid in the introduction of the "Centrifugal Sedimentation Analyzer CAPA-500" to the United States market. Being a cuvette centrifuge, it was a totally new product to potential customers. In order to operate it properly a series of questions had to be answered prior to running the instrument. These included how to properly sample the sample container, what dispersion liquid to use, what surfactant to add, how much energy to use to aid dispersion, etc. The need to answer these and other questions related to the set-up and operation of the instrument dictated the establishment of the Applications Laboratory.

In the early years, the testing of samples from prospective customers was the primary focus for the laboratory. With no established base of customers, it was critical to show the applicability of the new instrument to the customer's samples. Typically a customer would send 2-4 samples to the laboratory to be analyzed. In a very large percentage of the cases, the final purchasing decision was made based on the quality of these results. With an ever-increasing base of knowledge about sample preparation and

analysis, the business grew and prospered.

The first major expansion in the laboratory took place in 1987. At that time it was recognized that one of the barriers to Horiba's success was a lack of international recognition of Horiba and its products. A decision was made to attempt to develop some methods centered around Horiba's equipment. At the time, the American Society for Testing and Materials (ASTM) was selected as the venue to obtain the desired recognition. Hence, the ASTM committee D21.07 was approached to begin the long process. First a procedure was written to cover the Horiba products and then the arduous task of conducting multiple tests on multiple samples at multiple locations was begun. The staff of the Applications Laboratory spearheaded this major technical effort. The result of this effort was procedure ASTM C-1182 that was approved in 1991 and is currently still in use.

In 1989 Horiba Ltd. realized that laser light scattering was a key technology for particle sizing in the 1990's. This led to the development of the "Laser Particle Size Distribution Analyzer LA-500". The introduction of this new product caused some profound changes to the staffing and expectations for the applications laboratory. Additional staff members were hired and the staff was required to evolve from performing sample analysis to acting as consultants in particle size analysis. The questions changed dramatic from, "How do I analyze my sample?" to, "Where do I find information about refractive index, microscopy,



Optical system of the LA-920

粒径分布測定におけるアプリケーションラボの役割

< 黎明期 >

ホリバ・インスツルメンツ社(HII)のアプリケーション・ラボは、お客様に我々の製品を購入していただく際の事前評価を目的として1984年に設立された。その後の市場の急速な拡大に伴い、ラボの設備・人員が拡充され、役割もいろいろな方向に広がった。

遠心式粒度分布測定装置CAPA-500を米国市場へ拡販する目的で設立されたラボの使命は、お客様に我々の製品を正しく使っていただくためのお手伝いをするにあった。

試料の保持をどうするか、分散剤として何をを使うか、表面活性剤として何をを使うか、分散エネルギーはどれくらいが適当かなど、全ての質問にお答えし、お客様をサポートすることがその使命であった。

初めは、ご購入が有望なお客様からのサンプル対応がラボの主要な役割だった。まず、お客様から2~4種類のサンプルをお預かりし、分析する。得られた分析結果を通して装置の評価が下され、最終的に、高い確率で購入が決定された。

この頃、ビジネスを成功させるためには、ホリバブランドと製品自体の知名度を国際的に高める必要があった。そこでホリバの手法がASTMに掲載されるよう総力を挙げ、ついに1991年に承認された。それが、現在用いられている

sedimentation, etc.?”

The early 1990's saw the beginning of the quality movement in the United States and Europe. In order to respond to the new requirements, the laboratory took on new challenges. Issues such as QA procedures, sample logging procedures, statistical process control charting and others became new requirements for the laboratory.

<New Horiba Products

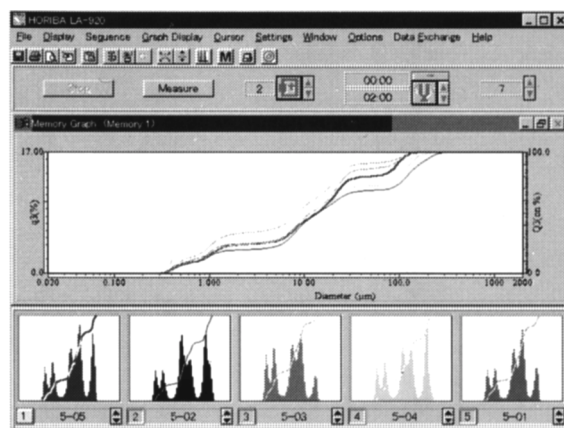
Required New Skills>

Another major shift in the role of the laboratory occurred in 1992 with the introduction on the “Laser Particle Size Distribution Analyzer LA-900”. This marked a major shift in the laboratory products that Horiba produced. For the first time Horiba offered products that were run by a personal computer (PC) rather than an embedded microprocessor. This philosophy has proven to be correct for the marketplace, but presented severe challenges for the applications laboratory. We had to develop a knowledge of computers, printers, software, etc. and we had to become expert enough in these matters to discuss them with customers.

The first step to address this challenge was to bring a knowledgeable person on staff to direct this effort. The person use close was Andy Gunewardena who continues to lead that effort today. We also stepped up the requirements we established for our laboratory analysis and began hiring people with good computer skills. We also selected good quality vendors whose products we integrated with our LA-900. This selection of high quality partners has served us well over the years, as customers have recognized the quality of our product offerings.

The ever-increasing need to provide telephone support to

our customers on a variety of issues was also recognized. Since our products are used by a variety of users from Ph.D. scientists to operators with high school diplomas, we must be able to answer many questions about our products. Correct and complete answers to users' questions are critical to the proper operation of our instrument and hence the customer's ability to generate good data with our equipment. In our case, we have a toll-free telephone number providing our



Screen display of the LA-920

customers access to our laboratory staff. The presence of knowledgeable friendly people to answer these questions is key to our success with customers. Over the years our ability to identify good people to handle this role has been crucial to our success.

粒度分布測定の基準方法(C-1182)である。

粒度分布計測の1990年代のキーテクノロジーがレーザ散乱法にあると気づいたホリバは、早速レーザ回折/散乱式粒度分布測定装置LA-500を開発した。これを契機に、ラボのスタッフは“このサンプルはどのように測れば良いのだろうか？”から“屈折率、顕微鏡像、沈降など関連情報はどこにあるのだろうか？”へと意識改革が急速に進んだ。一方、1990年代の初めには、米国とヨーロッパでは、品質に対する大きな波が押し寄せていた。お客様から品質関連の各種ドキュメントがラボに対しても要求されるようになった。

<新製品には新たな技術対応力が必要>

1992年にはパソコンを組み込んだレーザ回折/散乱式粒度分布測定装置LA-900を製品化した。この頃から、ラボのスタッフにはパソコンに関する知識を十分に備えておく必要が出てきた。優秀な科学技術者を採用し、高い知識を持つベンダーと協力することによって、製品自体の品質の高さとあいまってお客様に浸透していった。

お客様から寄せられた様々な問い合わせに対して、正しく完全にお応えし、製品を適正に使って良い結果を得ていただく。お客様とともに歩む姿勢こそが、今日の成功につながっている。

<Laboratory Provides Custom Support>

An important function that has developed over the years is that of providing custom support to key customers. This function may take the form of customized software, a customized sample preparation procedure, or a customized data presentation format. Americans have come to expect that any products they purchase can be tailored to meet their specific needs-particle sizing is no exception to this trend. For example a key customer who manufactures consumer products had a bimodal sample that required special analysis. Custom software was written to meet their needs. This yielded multiple orders from throughout the world. A major industrial product supplier needed to use their instrument as a portable analyzer. A custom shipping case was developed to prevent shipping damage. A well-known government agency needed to run some equipment from the inside of a van. The laboratory developed a system to power the equipment through a connection to the van's cigarette lighter. A global food supplier needed to study the stability of milk as a function of temperature. A temperature-controlled flow cell was developed to permit this study. There are hundreds of examples of the applications laboratory coming up with creative solutions to meet customers' needs.

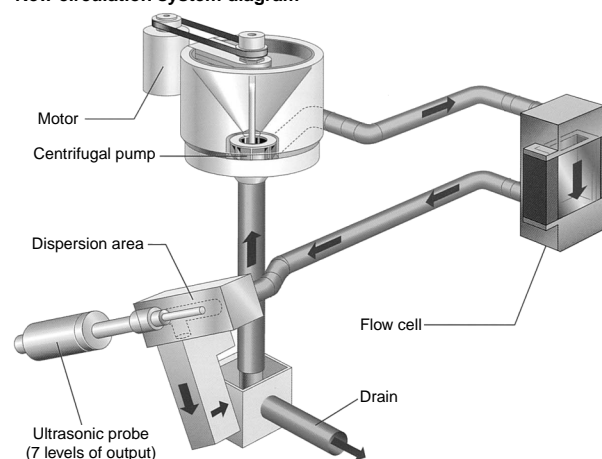
A new area of concern that has arisen recently is the idea of instrument validation. Many customers are concerned that as their instruments age, they will not perform as well as they did when they were new. A variety of organizations have created testing protocols to address this issue. The laboratory plays a lead role in developing and checking these methods. A key example of this is the ASTM cross-check program. Several times per month samples are run and compared to results from other laboratories around the world. A similar program in Europe called "proficiency testing" is also addressed. New ASTM methods are validated by

performing round-robin tests. We again play a key role in the evaluation of the new methods, as well as their applicability.

<Toward to the High Reliability and the Solution>

In 1997 a key decision was made by Horiba Instruments Inc. to achieve ISO-9001 certification by 1998. This decision had major repercussions for the applications laboratory: emphasis went from doing the job properly to properly documenting how the job was done. This new methodology was critical to the continued growth and success of laboratory products, but was sometimes difficult to implement. This shift from output to process forced us to develop the discipline to adopt and follow standard procedures in our applications laboratory.

New circulation system diagram



Sample circulation system for the LA-920

<お客様の満足を>

もう一つのキーポイントは特注対応である。特殊なソフト、サンプルの前処理、分析結果の処理など、ホリバが米国市場に進出できたのは、この対応力のおかげにほかならない。複合材料用の特殊分析法、カスタムソフト、ポータブル分析装置、輸送用梱包ケース、自動車搭載用電源、牛乳研究用の温度制御付フローセルなど、市場からの数えきれないほど様々な特殊な要求に対して、ラボは創造性をもって解決にあたってきた。

最近、分析装置の有効性の確認に大きな関心が集まってきている。この問題に対して、多くの試験研究機関が試験方法を提案している。例えば、ASTMの相互チェックプログラムがあり、これはヨーロッパの熟練度試験(proficiency testing)と類似している。ASTMでは持ち回り試験(grand robin tests)も行われている。ラボはこれらにも積極的に対応している。

<信頼性の向上とソリューションの提供に向けて>

H11では、1998年までに品質管理の国際基準ISO-9001を取得することが決定され、ラボの発展に欠くことができないと判断し、積極的に活動を展開してきた。その基本は、決められた手順にそって作業を進めることである。同じ頃、米国食品医薬局(FDA)は、分析結果の品質に関心を寄せ、計測機器メーカーに対し有効性を示す資料の作成を求めてきた。我々は薬品業界の助言を得てこれに応えた。このような要求に対し積極的にサービスする中から、逆に我々の製品に

At about this same time the laboratory was faced with a new challenge from the pharmaceutical industry. The U.S. Food and Drug Administration (FDA) became very concerned about the quality of data produced by analytical instruments in general. Due to this concern, they developed a methodology to determine proper performance. This required that the manufacturers of the equipment develop specific documents to validate the instrument performance. With the help of a consultant from the pharmaceutical industry, the laboratory was able to develop the methods and the documents to meet these requirements. This extensive effort allowed us to sell products to this critical and fast-growing industry. It has also evolved into a profitable business for Horiba, as we sell documents and service to perform IQ/OQ procedures. Providing this service to this industry has again helped us improve our knowledge about our products.



Michael C. Pohl, Ph.D.

Vice president
Horiba Instruments Inc.

The hallmark of the applications laboratory has been its ability to adapt to the changing market requirements in North and South America. American customers have come to expect instrument suppliers to provide complete solutions rather than just instruments. An instrument that does not provide meaningful data to the customer is viewed as a waste of money. The laboratory is constantly searching for new ways to improve the value of Horiba's products to the customer. We see this as one of the keys to success in the twenty-first century. Since we are striving to be a key supplier of these laboratory products in the new millennium, we will continue to emphasize the importance of the applications laboratory to our customers!

関する新たな知見も得られている。

ラボの評価基準は、北米市場のニーズの変化に対しいかに対応できるかである。お客様は、装置そのものよりも解決策を求めている。意味のあるデータを提供しない装置は、お金の無駄使い以外のなにものでもない。ラボは、お客様がホリバ製品に対して価値を高めていただくように常に新しい方法を模索している。これこそが21世紀を成功に導く鍵であり、新たな2000年代にも継続してキーサプライヤーとなりうるためには、ラボの役割がますます重要になっている。

(抄訳 編集部)