



# GPC STREAMLINER

## Compliance for polymers? You bet!

The areas of application for polymers and biopolymers are as varied as the macromolecules themselves. All industries are relying more and more on these long-chained all-rounders. Even in the pharmaceutical industry, polymers are being increasingly used. It often involves new developments in the fields of bio-absorbable products and proteins, and yet, quite classical polymers, such as acrylates, are still not indispensable here.

Especially in the sensitive environment of pharmaceutical safety, an adequate characterization of the starting materials and end-products, as well as a reliable and stable quality control, providing comparable results over a long period, is essential. As if the analysis of macromolecules in itself is not complex enough, there are also general requirements, for example, by various national authorities, of the analyst. Of course, the demands for traceability and complete documentation, validation and qualification are absolutely right and understandable.

In these times of increasing sample throughput, with detection methods and method combinations becoming more and more complex and with less staff in the laboratories, the fulfillment of these requirements starts to become a balancing act.



### What does this mean for PSS and its customers?

To only offer instruments, reference materials, columns, software, or even service analysis is too shortsighted. In order to satisfy these various demands in the laboratory consistently, real solutions and not just a collection of excellent products are needed. Intelligent and efficient service as well as competent and fast support from qualified professionals with relevant expertise is essential. Direct personal contact is clearly preferred compared to an anonymous service hotline.

This GPC Streamliner will give you an overview of the various solutions and services that PSS has in recent years developed, not only for the pharmaceutical industry. For example, please read about our Compliance Pack for WinGPC

software and about the various services, you can purchase along with a complete system, as well as the unique capabilities in application development and column service. In addition, our Analytical Services team provides a case study with an insight into the possibilities of contract analysis at PSS. For competent and easy introduction to GPC/SEC, PSS offers both standard training courses and customized training courses directly in the customer's laboratory.

Under each article, you will find the relevant expert, including a contact phone number and e-mail address to get competent advice quickly and easily. On the last page, as always, you will find an overview of the upcoming events where PSS are participating, as well as details of our training courses. We look forward to meeting you at one of these occasions!

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# Column Technology

## PSS services around columns and separation methods

PSS has been working for many years together with customers from regulated environments such as the pharmaceutical, biotechnology and medical technology industries. The experiences from these collaborations have been incorporated into a variety of PSS products and services.

Pre-requisite for the collaboration was among other things, the fact that PSS has worked for many years to the quality standards of DIN ISO 9001. All processes from purchasing to production are transparent and comprehensively documented.

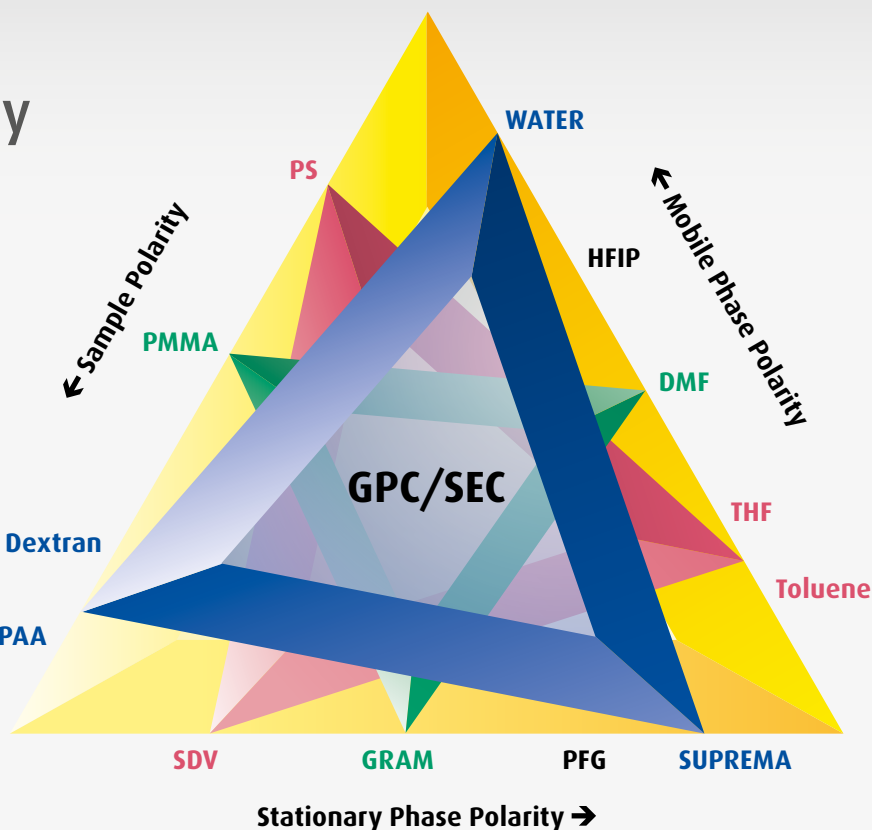
Additional arguments that speak for PSS as cooperation partner are:

- more than 25 years established as a manufacturer, specialized in polymers and GPC/SEC
- advanced laboratory infrastructure concerning synthesis and characterization
- strong collaborations with a variety of expert polymer chemists
- PSS produces the GPC/SEC gel materials themselves and is therefore able to assist its clients in the GPC/SEC method development and optimization of the application quickly and competently.

A few selected examples will show how PSS accommodates customer demands from the regulated environment today.

### Column Selection

Customers faced with the question of how to best analyze their new or modified samples/polymers by GPC/SEC, have the option to use the GPC/SEC columns selection service. After a detailed discussion with the customer, in which the sample characteristics and the customer requirements are discussed, PSS makes a column selection based on the customer-defined limiting criteria. From the variety of the gel materials (phases of different polarity, porosity and particle size) PSS will develop, for up to three representative samples, a GPC/SEC separation. PSS provides



a report with analysis conditions, chromatogram, measured results and a column recommendation.

### Method development

The PSS Polymer Competence Center can also offer its customers the complete development of GPC/SEC methods for their product ranges. This method development service portfolio includes the determination of the basic GPC/SEC method regarding the column, solvent and detectors. In addition, enhancement of the system with an appropriate high-end solution by coupling with molar mass sensitive detectors (MALLS or viscometer for determination of absolute molecular weights and intrinsic viscosities) or a method evaluation for substance identification and quantification is possible.

Issues related to production control, quality control or complex product de-formulation and structural analysis for R & D purposes, can therefore be developed for the customer. The method development contains robustness tests as well as the information for the quantification and also measurement uncertainty of the desired parameters. It is important that

the features of the polymer characterization and the method are considered because macromolecular characterization has different requirements and limitations compared to the analysis of low molecular weight substances. For example, to ensure that the chromatography is really interaction-free, PSS recommends control measurements on at least three different production batches of the same column type. Thus, the robustness of a method can be ensured regardless of normal fluctuations caused by production batch variations.

If required, then the entire method, including the instrumentation, the desired columns and calibration standards, is transferred to the customer, assembled in the customer's laboratory and together with the customer commissioned. The installation includes, on request, all necessary documentation for DQ, IQ, OQ and support for PQ.

### Batch reservations and exclusive gel material

If the customer would like to perform his analysis under comparable conditions over a long period and / or at many different locations, PSS can offer, for selected gel materials, the



possibility of batch reservation. Reservations can be made for both routine standard products or customized products. Exclusive customer batches are an advantage if the customer has specific issues regarding the sample analysis i.e. specific requirements relating to the sample, the chromatography or the method. In this way, customers receive their exclusive gel material with customized porosity and particle size in the desired amount. The cus-

tomers thus has, over many years, security of supply for its QC processes. Also batches from the standard production can be reserved by contract for customers in limited quantities, so that the customer can get material from the same batch over a specified period.

Also, before shipping the column(s) PSS can perform specific tests developed for the client application to ensure and document the column suitability.



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## Software solutions

### Validated, user-friendly, 21CFR11 compliant GPC / SEC software: PSS WinGPC MCDS

Software has to meet many everyday laboratory requirements. The tasks range from real-time data acquisition, sample management and interactive or automated data analysis to reporting for one or more users. The software should:

- support (and not hinder) the workflow in the lab
- reduce the burden on the user by supplying intelligent automation features
- provide the user with comprehensive and flexible processing options, that allow elucidation of structure-property relationships
- document method and evaluation parameters and characteristics of each sample including sample preparation.

Software is thus of crucial importance in the laboratory. With respect to the results, the user must be able to fully rely on the software, i.e. he must be sure that the right algorithms and procedures are applied. Considering that even a simple area calculation shows significant deviations in different HPLC programs {ref. Kuss, Kromidas: Quantification in LC/GC, 2009}, it is clear that for the more complex GPC / SEC routines with the non-linear calibrations, it is particularly important to be able to demonstrate the suitability and correctness of the software.

#### WinGPC software validation and verification tools

PSS has developed a dedicated validation procedure for WinGPC to verify and document that correct molar mass averages and distributions are obtained independent from the chromatographic system. This procedure is integrated in all versions WinGPC and can also be performed by the user simply by calling up the menu item. The procedure and the theoretical background are described in the online help and the green booklet that accompanies the user documentation.

Amongst other useful features that are part of all WinGPC Scientific versions that increase data security and traceability are:

- Database functionality with convenient sample management and powerful search options
- Calculation of plate count, asymmetry, baseline drift and noise, etc. according to various national and international standards
- Password access to WinGPC (one password for all users)
- Calculation of analysis precision for all results
- Logbook for WinGPC session details, system and evaluation messages
- Detailed comment functions for each sample for perfect traceability without requirement for a laboratory notebook



#### User rights for the user group WinGPC users

The default settings proposed by PSS can be edited to assign the lab specific permissions

## 21CFR11 Compliance: The WinGPC Compliance Pack

If additional requirements, for example by the U.S. Food & Drug Administration (FDA) or by other agencies, need to be met, the optional WinGPC Compliance Pack is available. This option makes WinGPC fully 21CFR11 compliant and adds:

- Controlled access restricted to users with a WinGPC account and login with a unique user name and password according to the company policy.
- Four different user levels with graduated privileges. The default settings proposed by PSS can be edited to assign the lab specific permissions.
- Electronic signatures (one or two levels with review option)
- An audit trail for each sample, which automatically documents the changes of calculation parameters.

The Compliance Pack can be purchased and added to the system at any time. It also applies to all available WinGPC modules such as light scattering, viscometry, mass spectrometry, etc. Since the Compliance Pack adds traceability and ease-of-use was the main driver during development, it is often used by the users, even if 21CFR11 compliance is not explicitly required. Although the sample audit trail can be disabled, e.g. for research projects, PSS generally recommends its activation. Since no extra work is required and everything is recorded automatically there are only advantages. The sample audit trail increases transparency and traceability dramatically, since e.g. the settings of the baseline or integration limits, which led to a certain result, are documented together with the raw data.

The different user levels that allow access to different privileges are a particular advantage for beginners. Only the menu items and options of the corresponding user level are accessible. This increases clarity, facilitates

learning of the software and offers increased data security. Beginners and advanced users alike can thus have more confidence in the results, making sure that accidental data manipulation is prohibited.

We would be happy to discuss the software needs and requirements of your lab and to assist you with the selection of the best choice! Please contact us, also for a webinar that shows the advantages of WinGPC in more detail.



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## Reference materials: GPC/SEC standards, Validation kits and more

As a rule, in a regulated environment, particular attention is usually paid to the measurement results. This also applies to the molar mass results from GPC/SEC analysis. If possible, the information in the analysis certificates should be well proven and include the measurement uncertainty. The traceability of certificate information is also important, i.e. the question whether the measurements are traceable to generally accepted reference values or at least to the values of an absolute method. Also of key importance is information on shelf life and stability as well as a long-term and timely quality control by the manufacturer over the entire sales and shelf life of the materials.

For a long time now, PSS has met the challenge for the demand of high-quality reference standards with accurate measurements. A permanent quality control of our different polymer batches available for sale is a matter of course.

In addition to the classical GPC/SEC reference standards (molar mass values from GPC/SEC measurements, calibration results based on light scattering), PSS has also more elaborate reference materials in the program. The diffe-

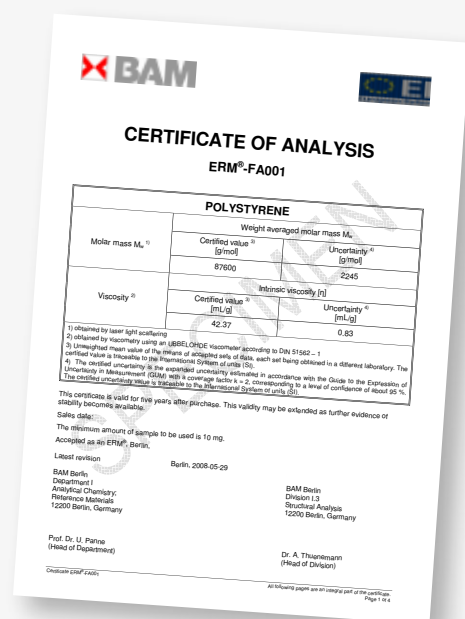
rence here refers to quality criteria in terms of peak purity, polydispersity, number and type of characterization methods used for molecular weight determination and the application area.

### DIN (German Institute for Standards) certified standards

Polymers characterized in the respective solvent (water or THF) according to GPC/SEC DIN requirements are the so-called DIN standards. In addition to GPC/SEC measurements (relative method), the molar masses of each polymer are determined with an absolute method such as MALLS (Mw), NMR, VPO (Mn) or MALDI (Mw, Mn). As well as the results, the experimental conditions are also specified. DIN standards are available as individual standards or kits.

### Round Robin Tested Reference Materials

The premium PSS reference materials are the so-called European reference materials, ERMs, (previously called certified reference materials "CRM") of the German Federal Institute for Material Research and Testing (BAM) in Berlin.



These ERM are round robin tested. The tests were coordinated by BAM and performed by selected laboratories under standardized conditions. In addition to the GPC/SEC experiments, the round robin tests cover also viscosity and light scattering measurements. Thus, the molar mass results of these three methods are independent from laboratory and operator. The results were statistically evaluated and beside the average values also the measurement uncertainties as well as the standard deviation  $\sigma$  of the round test results were quantified. In addition, the report also includes the results from NMR- and IR-measurements.

The ERMs are supplied with a detailed analysis report, which contains all the measurement results, analytical conditions and boundary conditions of the round robin test.

With this broad range of well-characterized reference standards, PSS is well positioned in the regulated environment and can help customers to obtain robust and reliable data.

### Special Polymers

Beside classic reference standards, the polymer synthesis division of PSS offers the manufacture of customized polymers. This service includes the synthesis and characterization of polymers with regard to molecular weight, molecular weight distribution and composition. Other polymer parameters may be added if needed.

All controlled "living" polymerization methods are available to manufacture the customized polymer according to topology or architecture (homopolymers, copolymers, comb or star polymers). If technically possible, the desired polymers can be varied over a wide molecular weight range and copolymers (block copolymers) over a large composition range. Hydrophilic-hydrophobic block copolymers are also possible, as well as labeled or end-functionalized homopolymers.

The synthesis capabilities also extend to biocompatible (e.g. hydrophilic-hydrophobic block copolymers used as phase transfer carrier systems for hydrophobic drugs) or biodegradable polymers such as polylactides. In this way, own reference materials for critical applications can be established.

### Validation kits

Validation kits allow the specific testing of complex systems and detectors as well as the determination of specific system and detector constants.

To validate a complete system, PSS EasyValid validation kits are available. With the help of aqueous or organic EasyValid kits, the performance of a GPC/SEC system in a holistic test can be easily checked and controlled. The kit contains an EasyValid validation column, test substances, as well as detailed instructions for the evaluation of various tests, including the limit and expectation values for the determination of the molecular weights of the test substances.

In addition, PSS offers validation kits for targeted testing of individual specialist detectors. The light scattering/viscometry validation kit consists of narrow and broad distribution polymer standards (aqueous applications: dextran; organic applications: polystyrene, PMMA). As well as the normal molar mass information,  $M_p$  from GPC/SEC and the Mark-Houwink constants  $K$  and  $\alpha$  from the viscosity measurements, the molar mass average values  $M_w$  and  $M_n$  from GPC/SEC, MALLS and viscometry are also provided. Thus, on-line viscosity and light scattering detectors can be checked.

With the help of the provided information, complex GPC-MALLS-viscosity detector couplings can be validated and corrected if necessary. For example, using the  $K$  and  $\alpha$ , it is possible to check and correct the offset of the viscosity detector compared to the concentration detector (RI or UV).



The MALDI kits are available as homologous polymers of different molecular weights or as a mix of different polar polymers. As well as enabling the measurement of the resolution of the spectrometer, they also help to select the appropriate matrix for a particular class of polymers. The certificates contain the comparison of the molar mass information from a relative method with two absolute methods based on MALDI, NMR, VPO or MALLS. In addition, the MALDI spectrum, and the MWD from GPC/SEC is provided.



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## Analytical Services for the Pharmaceutical Industry

Usually pharmaceutical products are associated with specific drug formulations, which start or support a healing process with preferably as few side effects as possible.

These drugs or drug combinations are defined, chemically pure substances that are either produced synthetically or derived from natural products.

There are also biopolymers, which are used quite successfully in medicine.

### Case study: molecular mass of hyaluronic acid:

A classic example is hyaluronic acids (HA) or their sodium salts (Na-HA). These are compo-

nents of the extracellular matrix of vertebrates and are still being extracted from rooster combs. In addition, hyaluronic acid is now also produced biotechnologically from non-animal sources. The average molecular weight can be very high and certainly more than one million daltons.

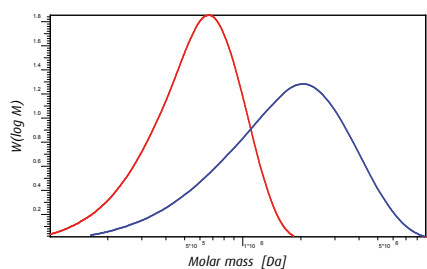
Hyaluronate preparations are widely used in human medicine. In the field of ophthalmology for the treatment of dry eyes (eye drops), in ophthalmic surgery to fill the vitreous during cataract surgery. In osteoarthritis, hyaluronic acid formulations are injected into the joints to produce a lubricating effect and thus to achieve temporary pain relief for patients. In cosmetic applications, hyaluronic acid supplements are used for anti-wrinkle injections

(wrinkle reduction) and shaping of the lips (enlargement). This desired effect is only temporary and only lasts a few months.

The physiological effectiveness is dependent on the average molecular weight and molecular weight distribution of hyaluronic acid/hyaluronate in the preparations. Therefore, this parameter is determined routinely. The analysis method usually used, is GPC/SEC coupled with light scattering, which provides absolute molecular weight information.

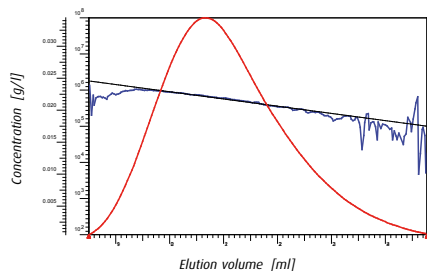
In the PSS contract analysis service laboratories, a method was developed and validated that enabled the characterization of the entire molecular weight spectrum of hyaluronate formulations.

Figure 1



molecular weight of hyaluronic acid determined by GPC/SEC with pullulan calibration (blue curve) and by GPC/SEC-MALLS (red curve)

Figure 2



Light scattering results of a hyaluronic acid: blue curve: molecular weights against elution volume, black curve: fit (weighted), red curve: concentration versus elution volume

As an example, a 0.8% sodium hyaluronate injection solution is investigated using GPC/SEC and GPC/SEC-MALLS coupling.

The GPC/SEC gives a molar mass of 2.03 million when using a pullulan standards calibration (see Figure 1, blue curve), whereas the GPC/SEC-MALLS coupling reports a molecular mass of 630,000 Da (see Figure 1, red curve and 2). This task requires that the  $dn/dc$  has already measured in batch mode.

An evaluation against a pullulan calibration overestimates the molecular weight significantly. In addition, the pullulan calibration can only done up to a molecular weight of about 2.5 million Da.

The content of hyaluronic acid in the formulation can also be established and/or verified from the recovery.

Therefore, for the pharmaceutical industry, the GPC/SEC multi-angle light scattering is the method of choice for the molecular weight characterization of hyaluronic acids.

### Other services

In addition to molecular mass determination, PSS can also perform substance identification and product de-formulation.

Method validation can be performed by the PSS service department according to a customer agreed validation plan.

### Analytical conditions:

Eluent:	phosphate buffer
Columns:	PSS SUPREMA 10 $\mu\text{m}$ column combination precolumn + 100 $\text{\AA}$ + 2 x 3000 $\text{\AA}$ (each 8x300 mm)
Detection:	PSS SLD7000 multi-angle light scattering detector, PSS SECcurity RI detector
Flow rate:	0.5 ml/min
Temperature:	35 $^{\circ}\text{C}$
Sample concentration:	0.5 - 2 mg/ml
Injection volume:	100 $\mu\text{l}$



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## PSS System Solutions: GPC/SEC IQ/OQ and more

### Interview with Peter Kilz, Head of Department for Systems, Software and Services

**Mr. Kilz, qualification, validation and documentation are essential for many laboratories today. How has PSS responded to the constantly growing demands in this area?**

The understandable demand to prove both the system suitability and the proper functioning of the system throughout its entire lifecycle, puts another burden on the user in the laboratory and significantly increases the workload. Without the support of the manufacturer i.e. by qualified experts, a sensible qualification with reasonable use of resources is difficult to achieve. On account of this, PSS considers the needs of regulated labs right from the start, i.e. at the design phase of new products, so that the products are immediately usable in the regulated sector and are supplied with detailed and complete documentation.

In addition, PSS has added new services, for example we provide full IQ/OQ services for customers who purchase a complete system.

These services are performed in close cooperation with the customer and under GPC/SEC operating conditions, not just under simple LC conditions as other manufacturers.

The solutions, which have been developed by PSS for system qualification, are also available for purchase by customers, who want do the qualification by themselves.

**What products and services has PSS developed especially for the regulated sector?**

In addition to reference materials for detector and method validation, we have also established European reference materials and primary standards. The characterization of these standards has been carried out by round robin tests according to ICH requirements. With PSS EasyValid, a holistic test tool that can demonstrate the suitability of a system to determine molar mass averages, we have developed a product specifically for the qualification of GPC/SEC systems.

In our WinGPC software, we have integrated many tools that assist during validation. For example, we have a unique feature that processes theoretical data on the WinGPC workstation after installation, which verifies that the data evaluation and processing is working properly.

In addition, it is possible to obtain system tests and printouts in accordance with important national and international standards and also to calculate precision of analysis, the measurement uncertainty, plate count and more. Included in the software are statistical evaluations of the equipment (e.g. determination of detector linearity, injector precision, flow-rate precision). This eliminates the need for data transfer and calculation in Excel as well as the validation of Excel sheets.

As well as IQ/OQ services for all PSS systems, we also offer method development and validation in addition to consulting and assistance in selecting the right column system,



**NEW**

**Now available as  
a Bioinert-System**

SECurity GPC/SEC-System

the appropriate parameters for quality control and methodologically meaningful boundaries (determination of acceptance criteria). Furthermore, it is possible to reserve columns from a specified batch and, if required, to a mutually agreeable specification. This ensures that measurements made over a long period of time and in different locations can be performed under identical conditions.

#### ***How is the scope of required services and products determined?***

This is done in close cooperation with the customer. If method development is required, the customer and the specialists from the PSS contract analysis and/or column material development departments create a multi-step project plan, containing feasibility studies and milestones. If it concerns the acquisition of a system, our experts from the systems and software department undertake a feasibility study and recommend the optimum system configuration. Based on these system components, PSS then makes a proposal for the IQ/OQ. This proposal consists of dedicated single component tests (metrological tests) and holistic tests to ensure that not only each component but also the overall system works correctly and completely reliable.

Subsequently, the proposal will be discussed with the customer and a detailed test plan is developed. In larger companies, this step

often includes participation by the validation department. Depending on the requirements of the company, the test plan will be extended or compressed.

At this time, we also discuss whether, in addition to the materials used by PSS for the qualification, other reference materials are needed. Also, the maintenance intervals and the extent of re-qualification are discussed. Both the maintenance and re-qualification, can be done by PSS.

At the end of this process, the test plan is fixed so that we can calculate the required amount of time for validation. There are large variations, sometimes the IQ/OQ only takes one day, but as a rule, more days are required, resulting in us being several days on site. The final quotation contains all items, from the materials to the services, so that the budget is strictly defined.

#### ***How does a PSS installation with IQ/OQ work?***

PSS sends the installation requirements and agrees the installation date with the customer. The first step is to install the system. Since the complete system is set-up and tested at PSS prior to delivery, the time requirement for this step is extremely low. After installation we start with system familiarization and the customer training. At this point, it is usually already possible to make real test measurements together with the users.

After a sufficient warm-up time for the stabilization of the instruments (for example overnight) the IQ/OQ starts. Metrological and holistic tests are performed by the PSS staff. All documents relating to the system are then added to the PSS Qualification Workbook provided with the system. The user can also insert additional documents and records here for subsequent maintenance and re-qualification. If required, we then have a closing meeting with the relevant validation department.

#### ***What are the benefits of an IQ/OQ done by PSS?***

Through our years of experience in this field, we were able to develop effective strategies. In addition, we perform the IQ/OQ (as well as the equipment maintenance) under true GPC/SEC conditions with the appropriate GPC/SEC solvents. By these means, we avoid, for example, damaging the columns by accidental contamination with the qualification solvent.

During the IQ/OQ, not only do we check the instrumental parameters, but also the complete GPC/SEC measurement process. We make sure that it is possible to measure molecular weight averages and distributions correctly. Of course, we qualify and verify all the GPC/SEC detectors used, for example, on-line viscosity and multi-angle light scattering detectors, something which other vendors either cannot or are not willing to do.

The qualifications are performed by PSS employees who work in the field of macromolecular analysis on a daily basis. This means that we have not only the system but also the environment in mind and hopefully can give valuable tips to reduce the daily burden in the laboratory. In this way we can for example help even with the PQ. Furthermore, we can draw on extensive material and literature to also help our users with general questions, e.g. regarding audit requirements.





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# PSS Events 2011/2012\*

## Face-to-face training

### GPC/SEC Training


-  October 25. - 27. 2011  
Tulane University; New Orleans, LA, USA
-  March 19. - 21. 2012

### Hands-on Visco/LS


-  June 27. bis 28. 2012

### Software Training

#### WinGPC ReportDesigner plus

-  September 10. 2012

#### WinGPC Basic Training

-  September 11. 2012


#### WinGPC Viscometry/Light Scattering

-  September 12. 2012

#### WinGPC SystemPilot

-  September 13. 2012


#### WinGPC Compliance Pack

-  September 14. 2012

Single day booking available.

## Usermeetings



### Column user meeting

-  November 08. 2011

All seminars in Mainz, Germany


## Web-based Training

### Webinars GPC/SEC Basic Training


-  October 19. - 20. 2011
-  November 16. - 17. 2011

### Webinars WinGPC refresher


#### Basic WinGPC Refresher:

-  November 2. 2011, 11:00 AM EDT

#### Advanced WinGPC Refresher:

-  November 3. 2011, 11:00 AM EDT

#### The Viscometry, Light Scattering, Triple detection WinGPC Refresher:

-  November 4. 2011, 11:00 AM EDT

## Conferences/Trade Shows

### March 11. - 15. 2012

PITTCON 2012  
Orange County Convention Center  
in Orlando, FL  
Booth

### March 25. - 29. 2012

ACS Spring National Meeting & Exposition  
in San Diego, CA  
Booth

### April 17. - 20. 2012

Analytica 2012 in München/Germany  
Hall A1, Booth 223

### June 18. - 22. 2012

ACHEMA 2012 in Frankfurt/Germany  
Hall 4.1 Booth P48

### August 19. - 23. 2012

ACS Fall National Meeting & Exposition  
in Philadelphia, PA  
Booth

\* Official language: English

## New PSS employee

### Since July 2011 Adrian Williams is working for PSS.


He is responsible for supporting our customers and distributors in East Europe and Asia.

Adrian Williams is a worldwide well known expert for GPC/SEC, Light scattering and viscometry.



**Adrian Williams**

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We are looking forward for an intensive co-operation!

## Contact

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## PSS has representatives in the following countries:

Austria, China, Croatia, Czech Republik., Denmark, Finland, France, Greece, Great Britain, India, Ireland, Israel, Italy, Japan, Korea (south), Mexico, Norway, Poland, Portugal, Russia, Slovakia, Slovenia, South Africa, Spain, Sweden, Taiwan, Turkey