

# Confluence

Bayshore Specialty Rx Newsletter



## Complex array of services behind clinical trials support



Clinical trials play an essential role in determining the safety and effectiveness of new medications. Typically lasting for months or years, clinical trials may involve only a few patients in one location or hundreds of patients scattered across the country. Running a clinical trial requires a great deal of planning and management, and Bayshore Specialty Rx is meeting the challenge with its comprehensive range of services that support pharmaceutical companies and clinical research organizations (CROs).

The company's pharmaceutical support services include clinical trials support, injection training, clinical consultants and home infusions. Bayshore also has a large network of English- and French-speaking nurses who specialize in pharmaceutical support programs, and its network of 25 community care clinics across Canada offers patients the option of receiving infusions and injections conveniently and comfortably.

Bayshore's state-of-the-art infusion pharmacy in Markham, Ont., provides a

high level of expertise in the preparation, storage and delivery of intravenous and injectable medications, including those that must be kept within a specific temperature range to remain effective. The company also distributes infusion equipment and supplies, including innovative, pre-programmed medication pumps.

Clinical trials are planned in conjunction with pharmaceutical companies and clinical research organizations (companies that manage clinical trials for pharmaceutical companies). It provides support services to these companies for investigational medical products (IMP) administration in the home or in its community clinic network. It works closely with the CRO's to coordinate nursing, pharmacy and shipping services, ensuring that strict administration and documentation schedules are met.

"We work with quite a few American and global clinical research organizations to support global clinical trials here in Canada," says Suzanne Nagy, Bayshore's Director of Pharmaceutical Services. "Our national network is part of our appeal. We can ensure the consistency of service across the country, which is critical for clinical trials.

Bayshore's national network of community care clinics is also available to physicians interested in running clinical trials but who do not have their own facility. "We charge a standard facility fee which includes the facility, the nurse, the supplies, documentation done by the nurse, and scheduling. This gives physicians who normally do not have the space

*(continued on back page)*

Bayshore Specialty Rx is a subsidiary of home and community health care provider Bayshore Home Health. We offer a wide range of infusion-related and pharmaceutical support services to clients such as government care programs, pharmaceutical companies and other health care organizations. Our goal is to improve patient care through an integrated approach to home and community infusion services.

### Infusion Pharmacy Services

Our state-of-the-art pharmacy specializes in the preparation, storage and delivery of infusion, injection and specialty medications used in areas such as anti-infection therapy, chemotherapy and TPN (total parenteral nutrition). We also distribute infusion equipment and supplies and provide support services in this area.

### Community Care Clinics

Our national network of 25 community care clinics, including 13 in Ontario, offers an alternative to the hospital setting for people who require infusion or injection of specialized drugs.

### Pharmaceutical Support Services

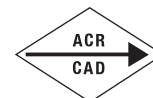
Assist pharmaceutical companies through support services that include specialized nursing, reimbursement programs, home infusions, injection training, clinical trials support and drug warehousing and distribution.

*Canadian owned and operated, Bayshore Home Health is the country's largest provider of home and community health care services, with more than 40 home care offices and 8,000 employees.*

COMPANY OVERVIEW



Bayshore Home Health, 2155 Dunwin Drive, Unit 10, Mississauga, Ontario L5L 4M1

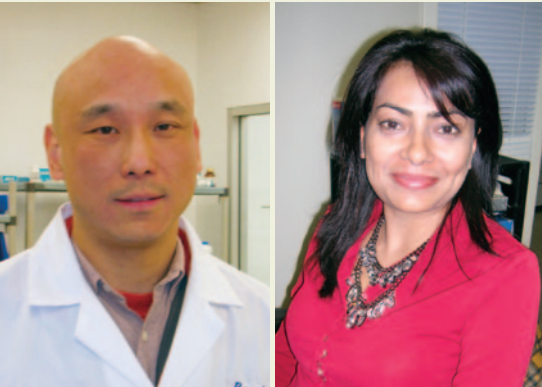


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# Clinical trials: The pharmacy perspective



Martin Chang, Clinical Pharmacist at Bayshore Specialty Rx's Infusion Pharmacy, and Mani Rahman, National Pharmaceutical Project Leader.

Mani Rahman, Bayshore Specialty Rx's National Pharmaceutical Project Leader, oversees the company's involvement in clinical trials. "There are a lot of logistics involved," she says – a modest statement, considering that some investigational products must be injected within three hours of preparation at the pharmacy.

To set up a clinical trial, Rahman pulls together several elements. "I usually start by finding out the service issues of the particular area – the proximity of the nurses, pharmacists and a local pharmacy that are able to assist us. Then we set up training dates for everyone."

The pharmaceutical companies provide training for each trial, including how to administer the product, documentation requirements, specimen processing and

which document distribution is needed.

Rahman monitors and manages the studies, including ongoing coordination between the pharmacies, Bayshore's nursing services, the pharmaceutical companies or CROs, and the pharmaceutical support services team at Bayshore.

Martin Chang, Clinical Pharmacist at the company's infusion pharmacy in Markham, Ont., ensures that the investigational products are prepared and shipped properly. "We receive the clinical trial orders from doctors, and we send out the medication and any supplies they need, such as tubing or pumps according to trial protocols, across Canada," he explains.

Transporting the product can be challenging, Chang says, because of the need to maintain a "cold chain," or temperature-controlled transportation, at every stage. Depending on how far the product is travelling, this could include delivery by commercial courier or local driver. In addition, the sites receiving the product must have a special refrigerator with temperature monitors and alarms, says Chang. "The average pharmacy wouldn't have the specialized refrigeration units that we use for the storage of investigational medical products that, or the training required."

Bayshore's team must respond quickly to any changes that arise. "We have a pharmacist on-call 24/7 – if problems arise, we're quick to resolve them," says Chang.

For more information, please contact [mrahman@bayshore.ca](mailto:mrahman@bayshore.ca)

## Clinical trials support (continued)

to conduct clinical trials the opportunity to expand their practice as lead investigators," explains Nagy.

At any time, Bayshore provides support for multiple local, national and global clinical trials. Currently, the smallest involves only two patients, while others involve dozens. Some of the studies only require Bayshore's services for a few days and others for three to four years.

Depending on the investigational medical product, patients may require drug administration as often as three times a day or only once a month. Bayshore's nursing services allow them to receive therapy in the comfort of their own homes or in our community clinic network.

When making home visits, the company's nurses perform health assessments and monitor the patient's condition in addition to administering the investigational product by infusion, injection, orally or transdermally. Nurses will also collect blood and other specimens for lab analysis and process the specimens for shipment or storage using portable centrifuges and dry ice. To ensure the highest quality of care, nurses adhere to international guidelines for Good Clinical Practice (GCP) for trials on pharmaceutical products.

"GCP is the international standard for clinical practice for clinical trials which has to be followed by all Bayshore nurses involved in clinical trials patient service. Nurses receive training, usually at the start of a clinical trial," says Nagy. "This will include protocol-specific training, documentation reviews, IMP administration and training for processing specimens for shipping to a central lab."

Because of its expertise and comprehensive services, Bayshore is uniquely positioned to support CRO clinical trials in Canada. "We have the people, pharmaceutical facility, knowledge, nursing support and pharmacists," says Martin Chang, Clinical Pharmacist at the company's infusion pharmacy. "We also have the capability to expand to handle more clinical trials. As they grow, we will grow."

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## COMMUNITY CARE CLINICS OFFER AN ALTERNATIVE TO HOSPITAL SETTING

Bayshore Specialty Rx operates 25 community care clinics across the country, including 13 in Ontario, that offer a comfortable environment and alternative to the traditional hospital setting for individuals who require infusion or injection of specialized drugs.

### WESTERN CANADA

Calgary / Kelowna / New Westminster / Regina  
Vancouver / Victoria / White Rock / Winnipeg

### ONTARIO

Barrie / Chatham / Hamilton / London  
Mississauga / Oshawa / Ottawa / Richmond Hill  
Sarnia / St. Catharines / Sudbury / Toronto  
Windsor

### QUEBEC

Pointe Claire

### THE MARITIMES

Halifax / Saint John

## PLEASE CONTACT US FOR MORE INFORMATION

For more information about any of the services mentioned in this newsletter, please contact Sahar Whelan at [swhelan@bayshore.ca](mailto:swhelan@bayshore.ca) (infusion pharmacy services) or Suzanne Nagy at [snagy@bayshore.ca](mailto:snagy@bayshore.ca) (community care clinics and pharmaceutical support services).

Confluence is published by Bayshore Specialty Rx for the information of its pharmaceutical services clients. For more information about this newsletter or to submit story ideas, please contact Mary Mamak at 1-800-668-9490, Ext. 339 or [mmamak@bayshore.ca](mailto:mmamak@bayshore.ca).

**Bayshore**  
Specialty Rx