

Building and designing the infusion device of the future

By Kenneth A. Fine

Traditional infusion therapies via a needle or catheter are sometimes superseded by less common drug infusions such as intramuscular injections and epidural routes. Until the 1980s, all these procedures were done in a hospital. But now the mounting pressure to control health care costs is leading to more in-home and outpatient infusion therapy considerations, where possible.

In addition, more novel infusion techniques and devices are being developed to administer a wide range of treatments including entirely new modalities, along with new and more effective drugs. Therapeutic agents are emerging that are more complex than soluble drugs. Crossing the blood/brain barrier is an important challenge with great potential for new treatment breakthroughs. Iontophoretics can diffuse ions into the body leaving fluid solutions behind. Gases can be infused to nourish biological materials until they are able to vascularize and grow. Biologics, including stem cells, gene therapy and recombinant therapeutic proteins may be used to treat a variety of medical conditions for which no other treatments are available.

Depending on the substance being administered, the degree of medical supervision required and the location inside the patient's body that must be reached, infusion devices may be as simple as an IV pump on a pole or much more high-tech, such as wearable and implantable devices. The most advanced systems that enable complicated applications or overcome unique challenges require a highly specialized approach to design, development, validation and manufacture. Some of the drug delivery issues these specialized designs overcome are temperature sensitivity, unstable and quickly perishable drugs or biologics and the sensitivity of the drug compounds with certain materials or pressure rates. These issues lead to innovations that have changed the landscape of infusion methods.

Going where no infusion device has gone before

For some applications, an implantable device is ideal. Downsizing their design is an important consideration: the smaller the device, the easier it is for the medical provider to implant and maintain, and the easier it is for the patient to live with. Yet shrinking the size of a device with complex functions creates new challenges. Batteries can be impossibly large for a tiny, complicated piece of equipment. In that case, pressure or chemical methods may be used to power the device. Frequently in an implantable device, a combination of chemical pressure and physics may be augmented with electronics to control the state and flow of the infusible solution.

Other design characteristics will be dictated by the rate, quantity and force of flow required. Different means of propelling the fluid are used for different solutions. CT scanning requires a relatively large, fast, forceful infusion of contrast medium. At the opposite extreme, some drugs are dispensed in minuscule doses, at a slow trickle. Either way consistent and precise controls are necessary. Design and manufacturing approaches are modified to meet specific device requirements, ranging from sourcing next-generation power supply technologies to integrating advanced flow metering techniques, along with obtaining raw materials that are specified as demanded by the properties of the infusate.

Drugs that cannot survive in contact with certain plastics need transport through devices made of alternative materials, which must

Numia Medical Technology LLC

84 Farrant Street
Newport, VT 05855

802-323-0101

www.numiamedical.com

6003 MicroFuse Dual Rate
6006 MicroFuse Rapid Rate
6005 MicroFuse Extended Rate

- ↳ Portable
- ↳ Quick setup
- ↳ Accuracy +/- 3%
- ↳ Cost-effective
- ↳ User-friendly



The choice for Clinical and Home Infusion

Watch the instructional video on our website

Approved as a NxStage System One Auxiliary



be specified and tested for efficacy. Temperature control is designed into many infusion pumps as well, providing necessary preservation of chemical properties or fluid dynamics.

Keeping pace with scientific achievements

The scientists developing new therapeutic agents are specialists in chemistry, pharmacology, genetics and life sciences. They are making monumental inroads for successful treatment of disease. Treatments and even curative remedies are emerging for intractable illnesses and injuries such as nerve damage, genetic diseases, COPD and others.

Delivering those treatments is another matter. Medical device developers — engineers, chemists, manufacturers — tackle different challenges. These specialists design customized infusion devices with appropriate size,

electronics, controls, power, monitors, metrics, physical properties, operation, maintenance and function. The FDA has rightfully added that more efforts must be made in the design phase to adequately study human factors. Medical device developers are putting more emphasis into designs that are intuitive for clinicians and patients, thus reducing or removing the risk of human error.

Medical drug researchers and biotech companies are responsible for testing the safety and effectiveness of the therapies they develop. They methodically test and confirm that the product meets all requirements to obtain regulatory approvals for these substances. Medical device companies assume responsibility for the safety and efficacy of the delivery mechanism while guiding it through testing and FDA approval. Some of these devices and drugs become a "combination device product," requiring the drug companies and device developers to work very closely to meet the demands of the "combination device" regulatory requirements.

Finally, there is the issue of cost. The technologies involved in making these infusion devices don't come cheap, but leaders in the industry are always looking for ways to leverage their expertise with cost-effective technologies where possible. The number of people needing some of these treatments is high, and costs have been prohibitive for many. By making them more affordable, we can improve patient compliance.

The potential promised by new medical treatments is astonishing. As scientists come up with new therapeutic agents, the question of appropriate delivery mechanisms must be ad-

ressed. Infusion devices are needed to dispense many of these new, potentially life-changing treatments, and medical device manufacturers are advancing rapidly to design and build implantables that can safely transport these trailblazing substances. The combined efforts of medical scientists, biotech companies and device designers and manufacturers will bring unprecedented benefits to disease treatments and cures.



Kenneth A. Fine is the president and co-founder of Proven Process Medical Devices. Fine has over 31 years of experience in the design and development of Class II and critical Class III electromechanical medical devices and equipment. His major areas of expertise include: electrical and soft-

ware design for medical systems; medical software development processes and quality systems; international and domestic quality standards; FDA GMP; new product development and product improvement management. Fine holds an MS degree in electrical engineering from Northeastern University and a BS degree in biomedical engineering from Boston University.

Share this story: dotmed.com/news/30454

DOTmed Registered Infusion Pumps Sales & Service Companies

For convenient links to these companies, go to www.dotmed.com and enter [DM 30456]. Names in boldface are Premium Listings.

Company (domestic)	Contact Name	City	State	Certified	DM100
MPI Medical	Arnold Wiesel	San Diego	CA	•	•
USOC Medical	All Youssef	Irvine	CA	•	•
CBE Medical, Inc.	Anwar Abdelqader	Anaheim	CA	•	
Pacific Medical	Andrew Bonnin	San Juan Capistrano	CA	•	•
Omega Surgical Supply, Inc.	Peter Brandvoid	Jacksonville	FL		
Hospira		Lake Forest	IL		
Baxter		Deerfield	IL		
Terrain Biomedical	Mark Waldrop	Elk Grove Village	IL	•	•
Medical Specialties Distributors	Nathaniel Green	Stoughton	MA		
Medical Equipment Dynamics	Garret Purrington	New Bedford	MA	•	•
Coast to Coast Medical	Kevin Blaser	Fall River	MA		x
PRM	Bob Gaw	Fall River	MA	•	•
Clinical Resources	Sue Graham	Bowson	SD		
Smiths Medical		Plymouth	MI		
Med-E-Quip Locators, Inc.	Bob Caples	Kirkwood	MO	•	•
Adepto Medical	Tommy Creal	Kansas City	MO	•	
Willow Medical	Shawn O'Donnell	Holly Springs	NC		
Global Inventory Management	Alison Fortin	Dover	NH	•	
Martab Medical	Scott Mancini	Allendale	NJ		
Biomedix Medical	Jason Ragazzo	Toughkenamon	PA	•	
Munet Medical	Dave Terry	Salt Lake City	UT	•	•
I.V. Technologies, Inc.	Walter Gallocher	Upperville	VA		
Auxo Medical	Jay Crabtree	Richmond	VA		•
Numia Medical Technology	Gail Ruggles	Newport	VT		
Company-International	Name	City	Country	Certified	DM 100
ANDA Medical, Inc.	Shane Barnes	Ottawa	Canada	•	•
PRASTON	Lukas Pien	Leszno	Poland	•	•