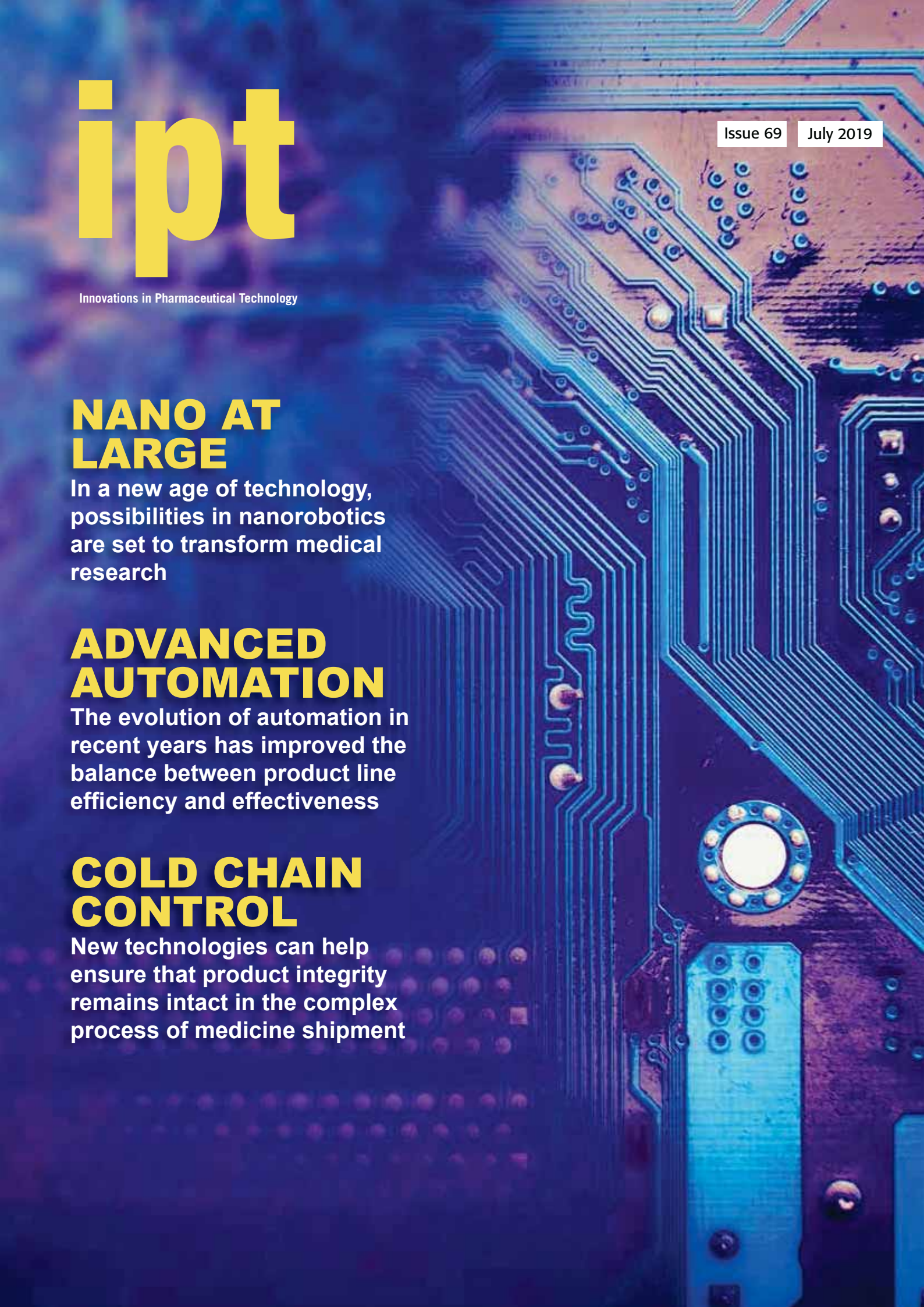

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Innovations in Pharmaceutical Technology

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NANO AT LARGE

In a new age of technology, possibilities in nanorobotics are set to transform medical research

ADVANCED AUTOMATION

The evolution of automation in recent years has improved the balance between product line efficiency and effectiveness

COLD CHAIN CONTROL

New technologies can help ensure that product integrity remains intact in the complex process of medicine shipment

The Case for an Integrated IRT

Organisations are currently faced with a choice between creating a surplus and delaying clinical trials, but an integrated free picking interactive response technology may be the answer to simplifying the supply chain

Bart Nicholson at Signant Health

Clinical trials hinge on patients having access to the supplies they need when they need them, and organisations often err so far on the side of caution they absorb exorbitant costs. Building a 'just in case' buffer of drugs can impact the return on investment (ROI) of any trial, and this is particularly true for expensive oncology investigational products and comparators.

However, it does not have to be this way. An integrated free picking (just-in-time) interactive response technology (IRT) interface can help companies reduce the costs of maintaining adequate buffers in their supply chain.

The Dilemma

At the start of every clinical trial, the supply team faces the dilemma of how much product will be needed. Too small a buffer and the sponsor may struggle to cover spikes in enrolment or other unexpected events, resulting in expensive delays. If too much product is produced, it will ultimately need to be destroyed, but only after accruing significant manufacturing, labelling, and storage costs.

When faced with the choice of a delayed trial or absorbing the costs of a surplus, most supply managers will overestimate the buffer.

Drug Pooling

One way of reducing the risk is through drug pooling. Rather than estimating the quantity of drugs needed for an individual trial, supply managers can calculate a buffer based on the whole programme or compound level. By having a buffer stock that can shift between studies, organisations can substantially reduce the total quantity needed to support a programme. This reduces the costs


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> By taking into account some key considerations, an appropriate system can be designed with relative ease

associated with drug wastage. Under a traditional inventory model, clinical supply teams use a clinical supply management (CSM) system to track manufacturing, labelling, and upstream supply chain activities. IRT is then used to manage trial supplies at the protocol level.

To introduce pooling in this model, an additional standalone supplies management system is normally introduced for depot supplies, which sits between the various IRTs. The downside to this approach is that there is yet another system to maintain, and, for each protocol brought online, there is a risk of reprogramming required within this additional system. Enabling a free picking (just-in-time) interface directly between the CSM and IRT eliminates the need for an additional standalone system.

How Does It Work?

Under a free picking (just-in-time) model, the CSM will assume ownership of depot level supplies and will be the primary interface for the actual personnel in the warehouse tasked with picking kits for shipments.

As IRT is a system with full visibility into patient schedules and site activity, it will continue to have ownership of the resupply logic used to generate shipment requests. However, differing from standard IRT setup, a free picking (just-in-time) model will involve the IRT requesting only by quantity instead of by specific kit number. This enables the warehouse to manually select which kits are to be shipped and record their selections into the CSM. The CSM will then update IRT as to which kit combination is being sent to which sites. With proper labelling and controls over supplies, drug pooling will now be enabled across multiple protocols.

Once kits have been allocated to a shipment, the supplies are released in IRT, and normal IRT handling for all downstream activities resumes (shipment receipt, allocation, expiry events, and more).

Two key benefits are clear to this way of working:

1. Simplified drug pooling across programmes, which translates into sizeable cost reductions
2. Simplification of each IRT instance, as depot level supplies management can be omitted from each build. Clinical supply teams will no longer need to be in and out of multiple IRT systems to view depot inventory

Key Considerations

Implementing an IRT free picking (just-in-time) interface does not have to be costly or complex. By taking into account some key considerations, an appropriate system can be designed with relative ease.

List or No List?

IRT free picking (just-in-time) does not have to be implemented at every depot location for the benefits to be realised. In most cases, the sponsor or distribution vendor will support just-in-time logic at primary distribution centres, with traditional orders being managed by the usual IRT method at regional sub-depot levels. Two ways of supporting this hybrid approach can be identified, and the appropriate choice will depend on the organisation's internal business processes.

In the 'no list' model, the IRT does not contain a master kit list, and all manufacturing and labelling occurs at the primary depots.

The sub-depots raise a quantity-based supplies request to the primary depots via the IRT. This information is transferred to the CSM system, which then transmits kit, lot, and expiry data for the products to be picked and shipped to the sub-depot. Once the goods are received, the sub-depot uses 'traditional' IRT logic to fulfil its own requests from sites (i.e., specific ordering by kit/lot).

Bart Nicholson has spent his career in the validated software industry in a variety of roles across multiple applications. Bart joined Signant Health's IRT team in 2011. He has an undergraduate degree in Computer Engineering from the University of Delaware, US, along with an MBA from Drexel's LeBow College of Business, US.

In the 'partial list' model, the IRT houses a portion of the master list, but this is only used at sub-depot level. Manufacturing and labelling can be carried out at a primary or sub-depot, and supply transfers between the two occur outside of the IRT. When products are received at the sub-depot, they are then released to sites in the IRT following the traditional process.

'Do Not Ship' Logic

IRT traditionally manages a 'do not ship' (DNS) value, which specifies how many days prior to expiry a kit is allowed to be included in the shipment. When the IRT generates a site order, the lot with the earliest expiry outside the DNS window is selected for inclusion. When implementing a free picking (just-in-time) interface, a decision has to be made as to whether the IRT will continue to track a DNS value or if this function will be owned elsewhere. In the event that the IRT will continue to track this value, depot-to-site shipments are straightforward and follow traditional IRT logic. In these cases, the IRT will simply include an earliest expiry date in the shipment request file based on the DNS value in the IRT. When kits are subsequently picked for inclusion in a shipment, this date needs to be accounted for.

Depot-to-depot transfers are handled in a slightly different way. Unlike depot-to-site shipments, the logic of choosing the closest expiry to the DNS window does not apply. Actually, the opposite is applicable as these are for lots with extended expiries that are being moved to sub-depots for subsequent site shipments. An extended DNS will need to be set up by the clinical supplies team in the IRT, or, alternatively, the clinical supply team may manually enter a date while requesting a transfer to guide the downstream picking activities.

To summarise, each implementation of a free picking (just-in-time) interface will need to decide how to account for DNS. Should the IRT continue to provide guidance in shipment requests? If so, traditional IRT logic should be implemented for depot-to-site shipments, with special consideration being added for depot-to-depot transfers. If not, this whole function can be omitted from the request files, but, of course, the fulfilment process will still need to account for upcoming expiry events as part of the picking process.

Partial or Failed Shipment Handling

When not linked to a free picking (just-in-time) interface, a core task of an IRT is to ensure shipment requests never exceed availability at the depot. Also, it will notify the clinical supply team when inventories run low.

These functions need to be replaced when the inventory management is taken out of the IRT and placed in the CSM system to create a free picking (just-in-time) interface. Typically, this monitoring is not difficult to do, but it is a key consideration during design to ensure an elegant solution can be supported.

Simplifying the Supply Chain

Clinical research is evolving at an incredible rate, making it an exciting yet competitive field to be working in. Maximising ROI and expediting progress on expensive drug studies has never been more important.

Implementing an IRT free picking (just-in-time) model can help organisations significantly reduce costs by managing supplies efficiently and with minimal risk over an entire clinical program or compound.

In a time of ever-complicated trial studies, this approach can simplify the supply chain process for study teams, resulting in increased efficiency.