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00:00:00,000 --> 00:00:09,840
Welcome to the ISPE podcast, shaping the future of pharma, where ISPE supports you on your journey, fueling innovation, sharing insights,

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00:00:09,840 --> 00:00:14,160
thought leadership, and empowering a global community to reimagine what's possible.

3
00:00:15,275 --> 00:00:20,555
Hello, and welcome to the ISPE podcast, shaping the future of pharma.

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00:00:21,035 --> 00:00:22,795
I'm Bob Chew, your host.

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00:00:22,955 --> 00:00:32,880
And today, we have another episode where we'll be sharing the latest insights and thought leadership on manufacturing technology, supply chains,

6
00:00:32,880 --> 00:00:36,880
and regulatory trends impacting the pharmaceutical industry.

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00:00:37,280 --> 00:00:43,680
You will hear directly from the innovators, experts, and professionals driving progress and shaping the future.

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00:00:44,405 --> 00:00:48,885
Thank you again for joining us, and now let's dive into this episode.

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00:00:49,525 --> 00:00:58,165
Our topic today is Bayer AG's SOLIDA-1 facility of the year award category winning facility.

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00:00:59,040 --> 00:01:08,240
To share more about this topic, I would like to welcome Juergen Wiedemann, Head of Pharma Technology Systems and Christophe

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00:01:08,240 --> 00:01:12,635
Ebbecke, Venture Manager, both of Bayer AG.

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00:01:12,955 --> 00:01:14,715
Welcome to the podcast, gentlemen.

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00:01:14,715 --> 00:01:15,595
Hi, Bob.

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00:01:15,595 --> 00:01:16,155
Nice to be

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00:01:16,155 --> 00:01:16,715
here.

16
00:01:17,515 --> 00:01:17,995
Yeah.

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00:01:17,995 --> 00:01:18,875
Thank you very much.

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00:01:18,875 --> 00:01:21,115
Appreciate the chance, to be here today.

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00:01:21,355 --> 00:01:31,310
Well, it's great to have you on, and let's start off by giving our audience an overview of this facility, the project, the why and

20
00:01:31,310 --> 00:01:32,030
the what.

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00:01:32,190 --> 00:01:40,110
Bayer SOLIDA-1, and you can see there isn't much fantasy in the name because SOLIDA comes from the SOLIDA production.

22
00:01:40,825 --> 00:01:50,585
It is a new launch and supply facility for all nonhormonal SOLIDA products Bayer will have in the next

23
00:01:50,905 --> 00:01:52,585
ten, twenty, thirty years.

24
00:01:53,510 --> 00:02:03,110
And basically, it, over the next years will, in this role, replace existing facility, which is

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00:02:03,110 --> 00:02:05,750
from the beginning of the eighties, got old.

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00:02:06,225 --> 00:02:16,065
And so a few years ago, the decision was taken instead of trying to, make the old facility new, we go for a new facility and takes the

27
00:02:16,065 --> 00:02:25,910
opportunity, yeah, to, build a new facility and to also take the opportunity to think about what

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00:02:25,910 --> 00:02:28,710
might be the right facility for the future.

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00:02:29,910 --> 00:02:31,670
Why is it in Leverkusen?

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00:02:31,670 --> 00:02:41,585
It is because we have development and production on the same location, and that gives you and we will have talk about this probably later that gives you

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00:02:41,585 --> 00:02:46,065
a big advantage in the timeline you need to bring product to the market.

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00:02:46,225 --> 00:02:46,465
Okay.

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00:02:48,280 --> 00:02:56,920
The SOLIDA-1 received recognition in both operational excellence and Pharma 4.0.

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00:02:57,560 --> 00:03:03,720
What makes this facility unique, and what do you believe most impressed the judges?

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00:03:04,175 --> 00:03:09,135
On the second part of the question, to be honest, I can only speculate.

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00:03:10,415 --> 00:03:16,095
But what makes SOLIDA-1 unique is not, I think, one individual technology.

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00:03:16,175 --> 00:03:23,980

It is probably that SOLIDA in pharmaceutical production were completely reengineered throughout the project.

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00:03:25,180 --> 00:03:28,140

Nothing was just copied to go the easy way.

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00:03:28,380 --> 00:03:33,855

Everything was challenged and discussed, like, do you have vertical flow or horizontal flow?

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00:03:33,855 --> 00:03:37,135

Is a recipe in the machine or in the MES system?

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00:03:37,455 --> 00:03:40,815

Do we need to improve equipment for better cleanability?

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00:03:41,375 --> 00:03:44,015

How is the maintenance concept in the future?

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00:03:44,175 --> 00:03:48,810

Where do we need what availability of equipment or even redundancy?

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00:03:48,970 --> 00:03:50,410

How to automate?

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00:03:50,410 --> 00:03:52,810

How to get data out of the machine?

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00:03:53,130 --> 00:04:02,985

So there's a lot of things where we, basically very often did Pioneer work if we could not find something, could

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00:04:02,985 --> 00:04:05,065

not find something that is really good.

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00:04:05,625 --> 00:04:14,825

Basically, good existing solutions were optimized, but a lot of new solutions were developed, resulting in consequent design principles, modularity,

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00:04:16,830 --> 00:04:26,590

ballroom concept, the full automation concept, full access to data and information sounds easy, but if you really want to do it, it gets horrible and

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00:04:26,590 --> 00:04:27,150

complicated.

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00:04:28,085 --> 00:04:33,685

And all that as a major condition for future proof, factory.

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00:04:34,165 --> 00:04:43,770

Did this, analysis, this sort of requirements definition and concept design effort, Was that longer

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00:04:43,770 --> 00:04:46,090

than a normal project?

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00:04:46,490 --> 00:04:51,130

And do you think you got the benefits of that extra effort?

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00:04:51,370 --> 00:04:51,850

Yeah.

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00:04:51,850 --> 00:05:00,985

We, what we did is, before we started with the investment project itself, upfront, we took our time to make

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00:05:00,985 --> 00:05:06,905

feasibility studies to investigate the machines of the different suppliers.

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00:05:06,905 --> 00:05:08,985

We did really test runs with material.

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00:05:09,650 --> 00:05:19,650

For example, we looked into all the continuous production equipment that was at that time available, checked it, and did test runs,

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00:05:19,650 --> 00:05:22,610

and figured out what is advantage and disadvantage.

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00:05:23,650 --> 00:05:32,065

Because when you build a new facility that is maybe a once in a decade's opportunity to change sits.

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00:05:32,305 --> 00:05:32,785

Yeah?

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00:05:32,785 --> 00:05:37,265

So, I just said that Leverkusen was built in the beginning of the eighties.

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00:05:37,720 --> 00:05:47,240

We are now in 2026, forty years down the road at least, which means that maybe the next SOLIDA-1 comes in forty years

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00:05:47,240 --> 00:05:47,880

again.

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00:05:48,280 --> 00:05:54,445

And if we would only copy something, we would have in forty years something that is nearly a 100 years old.

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00:05:54,685 --> 00:05:55,245

Yeah?

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00:05:55,245 --> 00:05:58,605

So and I think that is what really the major driver.

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00:05:58,605 --> 00:06:06,765

And we got, especially the order from the management not to just copy but rethink SOLIDA production.

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00:06:07,690 --> 00:06:09,450

Well, that's really fantastic.

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00:06:10,330 --> 00:06:17,290

Many pharmaceutical manufacturers struggle to balance speed, flexibility, and quality.

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00:06:17,770 --> 00:06:27,335

What challenge was Bayer trying to solve with SOLIDA-1, and how did that vision shape the design of the facility?

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00:06:27,655 --> 00:06:28,775

Great question.

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00:06:29,335 --> 00:06:36,720

And the conventional wisdom is that you have to choose between speed, flexibility, and cost.

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00:06:36,720 --> 00:06:44,800

And most pharmaceutical manufacturing plants that we see today follow that logic, and they're optimized for a specific purpose.

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00:06:45,905 --> 00:06:50,865

A fixed product, a specific technology, or a range of capacity.

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00:06:51,745 --> 00:07:01,660

With SOLIDA-1, we have decided to take a different approach, believing that, technology allows us

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00:07:01,660 --> 00:07:07,580

to reach all these schools without being forced to accept the trade off.

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00:07:09,660 --> 00:07:14,620

And so we engineered SOLIDA-1 for three core goals.

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00:07:15,935 --> 00:07:25,295

First, bring drugs to patients as fast as possible, meaning we needed rapid product launches and flexible, scalable

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00:07:25,295 --> 00:07:26,175

supply.

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00:07:27,375 --> 00:07:37,270

We wanted to deliver the highest quality and also achieve competitive cost, and not only for one specific product, but

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00:07:37,270 --> 00:07:42,710

as a manufacturing platform for our evolving internal and external pipeline.

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00:07:43,830 --> 00:07:53,725

And to move beyond this traditional trade off and achieve the goal of you know basically achieving all three, we took two

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00:07:53,725 --> 00:07:54,605

main levers.

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00:07:54,605 --> 00:08:04,240

Number one, multilevel modularity, which allows SOLIDA-1 to evolve in line with pipeline and

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00:08:04,240 --> 00:08:05,600

market requirements.

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00:08:06,640 --> 00:08:13,600

And we can adapt SOLIDA-1 for different products, technologies, and also capacity requirements.

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00:08:15,065 --> 00:08:24,105

And number two, second lever, by utilizing the potential of automation and digital integration in order to,

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00:08:24,745 --> 00:08:33,860

manage the complexity of a modular, multiproduct facility and still achieve a high level of efficiency.

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00:08:35,060 --> 00:08:44,745

And the result was honestly not your standard production facility, but it was rather a manufacturing platform which

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00:08:44,745 --> 00:08:51,945

will and is constantly evolving and will probably look very different in ten years compared to today.

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00:08:52,105 --> 00:08:58,345

I know a lot of projects get very ambitious around automation and digital integration.

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00:08:59,190 --> 00:09:03,750

And in some cases it really brings the project to its knees.

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00:09:04,630 --> 00:09:13,430

How did you overcome the complexity of automation and digital integration in order to achieve

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00:09:13,430 --> 00:09:17,225
your speed to project delivery?

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00:09:17,545 --> 00:09:27,545
Bob, to be honest, before we started SOLIDA-1 and we did all these feasibility studies, we did not only do a feasibility study when it comes

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00:09:27,545 --> 00:09:31,740
to how does a machine look like or how does a factory look like.

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00:09:31,980 --> 00:09:41,820
We also interviewed about, 12 engineering companies, and we visited, I would say, at least 10 sites, new construction sites

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00:09:41,820 --> 00:09:43,500
of, big peer companies.

101
00:09:44,325 --> 00:09:54,005
And our target was not only to see what do they do technically, but also how do you set up a project that you do not die in the

102
00:09:54,005 --> 00:09:54,725
project.

103
00:09:55,285 --> 00:09:55,845
Yeah.

104
00:09:56,005 --> 00:10:05,520
And because experience was that it is more common that big projects have big problems and not the other way

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00:10:05,520 --> 00:10:06,160
around.

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00:10:06,320 --> 00:10:16,135
For example, what we figured out is to have a water damage in the last months of the project before CNQ

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00:10:16,215 --> 00:10:17,975
seems to be the normal case.

108
00:10:18,535 --> 00:10:18,855

Yeah?

109

00:10:18,855 --> 00:10:20,135

It happened to me.

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00:10:20,375 --> 00:10:20,855

Yeah?

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00:10:20,855 --> 00:10:26,615

Some idiot leaves some valve open, and the water goes into your clean room walls.

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00:10:26,870 --> 00:10:27,430

Yeah?

113

00:10:27,590 --> 00:10:28,950

It seems to be normal.

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00:10:28,950 --> 00:10:29,430

Yeah?

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00:10:29,590 --> 00:10:37,510

And that was something, for example, where we thought about if this happens to everyone, you need to think about it.

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00:10:37,510 --> 00:10:45,285

And that, for example, was the reason that we try to have no water lines on top of the cleanroom walls.

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00:10:45,765 --> 00:10:46,325

Yeah?

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00:10:46,725 --> 00:10:56,090

And there design things with which you can increase the probability of success of a

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00:10:56,090 --> 00:10:59,850

project from the design, but also from the organization.

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00:11:00,170 --> 00:11:00,650

Yeah?

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00:11:01,050 --> 00:11:10,895

And so that was just an example where we saw how others work we also learned what should we do different in

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00:11:10,895 --> 00:11:15,455

order to increase the probability of success.

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00:11:15,535 --> 00:11:17,375

We'll never say it on a project.

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00:11:17,375 --> 00:11:18,015

That's sure.

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00:11:18,015 --> 00:11:19,775

Because things happen.

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00:11:19,775 --> 00:11:20,255

Yeah?

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00:11:20,495 --> 00:11:22,575

But he can increase the probability.

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00:11:22,920 --> 00:11:28,680

And the other thing is, probably later on we talk about how you organize your project.

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00:11:29,080 --> 00:11:32,920

Also, there we did go a little bit different approach.

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00:11:32,920 --> 00:11:42,615

For example, we invited the peer companies at the beginning of FEL two, the partner companies for the construction.

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00:11:43,015 --> 00:11:50,295

And we used already the execution companies starting FEL two to help us to plan the facility.

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00:11:50,970 --> 00:11:51,530

Yeah?

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00:11:51,530 --> 00:11:56,810

Normally, do a planning, then you go through a bidding process, and then you find your partners.

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00:11:56,810 --> 00:11:57,050

Yeah?

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00:11:57,050 --> 00:12:03,370

We did this at least months earlier when, if not a year earlier.

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00:12:03,450 --> 00:12:03,610

Yeah?

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00:12:04,275 --> 00:12:05,875

And so that was something.

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00:12:05,875 --> 00:12:09,715

So there were a lot of lessons learned out of this investigation.

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00:12:10,355 --> 00:12:14,115

What can increase your probability, also in automation.

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00:12:14,755 --> 00:12:23,440

And, of course, sometimes it's good you don't know how complicated something is because maybe otherwise you would not have started it.

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00:12:23,440 --> 00:12:24,000

Yeah?

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00:12:24,240 --> 00:12:30,080

And so we did not face the problems we expected, but, of course, we faced other problems.

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00:12:30,355 --> 00:12:30,995

Yeah?

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00:12:31,475 --> 00:12:37,475

But I I think, of course, you can go the easy way.

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00:12:37,475 --> 00:12:46,850

But as I said, if you build a new facility maybe every twenty, thirty, forty years, I think whatever problems you face in a

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00:12:46,850 --> 00:12:52,290

project, not to change something is probably the biggest fault.

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00:12:52,770 --> 00:12:54,050

That's, yeah, that's great.

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00:12:54,050 --> 00:12:57,375

And maybe I can add one one, aspect.

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00:12:57,375 --> 00:13:02,335

I think it's a healthy level of, pragmatism in the project team as well.

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00:13:02,975 --> 00:13:08,335

That, yes, as Jorgen said, you don't shy away from the difficult, topics.

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00:13:08,335 --> 00:13:09,535

You know, try out new things.

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00:13:10,590 --> 00:13:16,590

But, I guess sometimes it's important to not get stuck in the details and try to force solutions.

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00:13:17,070 --> 00:13:26,465

But, go for pragmatic solutions, try to apply technologies that are proven, bring them to your problem, and, achieve something maybe

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00:13:26,465 --> 00:13:33,585

that's good enough that gets you there, but that allows you to move forward anyways.

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00:13:33,585 --> 00:13:38,225

And I think that's something that the team definitely brought to the table from the beginning.

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00:13:38,625 --> 00:13:39,265

That's great.

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00:13:40,050 --> 00:13:47,170

You describe SLETA-one as a modular and adaptable manufacturing platform.

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00:13:47,810 --> 00:13:55,915

Can you explain what that means in practice and why modularity is becoming so important for the future of pharmaceutical manufacturing.

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00:13:55,915 --> 00:14:05,915

Well, we designed SOLIDA-1 from the ground up to be able to constantly evolve in line with pipeline, product, and market

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00:14:05,915 --> 00:14:06,475

demands.

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00:14:07,520 --> 00:14:14,960

Because in recent years, it has become increasingly more volatile and difficult to predict these factors.

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00:14:15,680 --> 00:14:25,455

And what this required is a holistic modularity strategy, which in SOLIDA-1 extends from the total facility level down to the

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00:14:25,455 --> 00:14:29,535

individual process unit on the manufacturing level.

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00:14:30,415 --> 00:14:40,070

The facility itself is designed as a series of independent modules, which each serve a specific function, production, logistics,

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00:14:40,070 --> 00:14:41,030

utilities.

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00:14:41,670 --> 00:14:50,310

And the modules are connected by a central spine that serves as the backbone for material and, personnel flow.

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00:14:50,895 --> 00:15:00,015

The spine is extendable in both directions, which allows us to add modules stepwise as they are needed, which

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00:15:00,015 --> 00:15:06,360

significantly minimizes the upfront investment risk, for the company.

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00:15:07,240 --> 00:15:17,000

Going down to the modules themselves, they are also designed with a standardized repeatable layout, which concentrates all support functions and

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00:15:17,000 --> 00:15:26,585

utilities at the front of the module, and creates an open production area in the back area of the module facing away from the spine

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00:15:27,065 --> 00:15:31,945

that can be used to design, process, and manufacturing environment freely.

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00:15:32,540 --> 00:15:42,140

And this creates a standardized blueprint that, you know, we can reuse to copy and paste, expand new modules,

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00:15:43,100 --> 00:15:48,985

which helps us to be significantly faster and also more cost efficient.

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00:15:51,145 --> 00:16:00,985

A new module can be commercially ready in roughly two years, including qualification, and that's about a full year quicker than, at a

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00:16:00,985 --> 00:16:02,905

traditional, facility.

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00:16:03,680 --> 00:16:09,120

And it also allows us about 25% in cost savings compared to traditional plants.

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00:16:09,680 --> 00:16:14,480

And then moving down to the, you know, manufacturing, the process level.

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00:16:15,760 --> 00:16:25,145

Within the production area, we are creating modularity by using standalone process units, that are connected

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00:16:25,145 --> 00:16:35,110

flexibly using robots and AGVs, and that allows us to adapt and change manufacturing processes

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00:16:35,990 --> 00:16:38,630

without having to reconfigure the site.

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00:16:38,950 --> 00:16:48,575

And it also allows us to replace single pieces of equipment and, manufacturing equipment without really adapting

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00:16:48,575 --> 00:16:51,375
the building or the module itself.

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00:16:52,095 --> 00:17:01,055
The facility is designed to reduce time to market by up to a year while supporting everything from clinical production to commercial scale manufacturing.

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00:17:01,890 --> 00:17:08,050
How does SOLIDA-1 enable that faster path from development to patient access?

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00:17:08,370 --> 00:17:12,370
Yeah, SOLIDA-1, there's no magic behind this.

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00:17:14,985 --> 00:17:16,185
That's the truth.

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00:17:16,425 --> 00:17:26,265
SOLIDA-1 accelerates the path from development to the patient by ensuring, continuous transition, especially on the interface from clinical

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00:17:26,265 --> 00:17:29,305
development to, commercial production.

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00:17:29,940 --> 00:17:39,700
And that starts, for example, with the colocation of clinical supply and commercial manufacturing in one location where you, for example, do not have to repeat

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00:17:39,700 --> 00:17:44,115
stability studies if you do both at the same location.

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00:17:44,755 --> 00:17:45,075
Yeah?

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00:17:45,075 --> 00:17:47,795
And that saves a lot of time and, of course, money.

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00:17:48,275 --> 00:17:58,100

Furthermore, the equipment in the different scale, yeah, so in the commercial scale or in the clinical supply, we have developed a concept that they

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00:17:58,100 --> 00:17:59,540

match to each other.

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00:18:01,540 --> 00:18:08,820

So from the equipment type, so that, the tech transfer, you can reduce the risk of problems there.

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00:18:09,275 --> 00:18:13,675

And bad surprises you may have if the equipment does not fit to each other.

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00:18:13,835 --> 00:18:14,395

Yeah?

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00:18:14,795 --> 00:18:24,670

And, again, the colocation not only pays off with the regulatory authorities, but also, of course, since the information needs to flow

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00:18:24,670 --> 00:18:33,870

over a few meters from one colleague to the other in those directions, from production to clinical supply or the other way around,

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00:18:34,605 --> 00:18:44,285

The probability that they talk about something and they understand what is going on in the other plant is

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00:18:44,285 --> 00:18:47,005

very high because we talk about meters.

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00:18:47,005 --> 00:18:51,590

And they probably meet during, they even meet for the next lunch anyhow.

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00:18:51,990 --> 00:19:01,985

So I think that is something you can hard measure, but information flow between people who meet during lunch is, of course, better than people who might be hundreds

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00:19:01,985 --> 00:19:09,505

of thousands miles away from each other, yeah, where theoretically the information flows, but in reality it does not work.

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00:19:10,385 --> 00:19:20,100

And the high level of data availability starting from the first batch, that of course supports scale up modeling,

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00:19:20,100 --> 00:19:22,820

process optimization and tech transfer.

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00:19:23,220 --> 00:19:33,155

For example, during the tech transfer of the first product in SOLIDA-1, the modeling of the process parameters in the fluid bed granulator started already

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00:19:33,155 --> 00:19:40,675

during the last minutes of the first batch when the material not even has left the fluid bed granulator.

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00:19:40,915 --> 00:19:41,475

Yeah?

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00:19:41,475 --> 00:19:51,060

Because the data available and in the same moment somebody was sitting in Berlin and starting his modeling machine with the data he got from the machine.

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00:19:51,460 --> 00:19:52,180

Yeah.

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00:19:52,180 --> 00:20:02,155

So it's, I think, close proximity and regulatory advantages together with, very

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00:20:02,155 --> 00:20:05,035

uncomplicated information flow.

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00:20:05,035 --> 00:20:10,315

That are the main levers, which bring the product, faster through the patient.

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00:20:10,395 --> 00:20:20,130

Did I just, hear that maybe there was digital twins, either of the equipment, the process, or perhaps both in play here?

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00:20:20,290 --> 00:20:20,690

Yeah.

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00:20:20,690 --> 00:20:27,330

The word, digital twin is something when you ask a lot of people, you get different answers.

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00:20:27,330 --> 00:20:28,530

What is a digital twin?

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00:20:29,445 --> 00:20:39,365

When it comes to the single machine, of course, you have models of, for example, especially the fluid bed granulator of how does a fluid

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00:20:39,365 --> 00:20:40,725

bed granulator work.

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00:20:40,725 --> 00:20:43,445

That is a digital twin of the machine itself.

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00:20:44,220 --> 00:20:53,900

But also during the project, we, use something you can call a digital twin, where, for example, we had a

223

00:20:53,900 --> 00:20:56,860

three-d model of the facility.

224

00:20:57,665 --> 00:21:01,345

But not only for the sake of having a three-d model.

225

00:21:01,665 --> 00:21:06,865

And then we, transferred this three-d model into gaming software.

226

00:21:07,905 --> 00:21:17,800

So you could run through, you could really run through SOLIDA-1 Play Operator, And that we used, during the design phase and when

227

00:21:17,800 --> 00:21:27,640

the facility was not finished, to, optimize, the construction and the planning, together with the

228

00:21:27,640 --> 00:21:28,200
operators.

229

00:21:29,075 --> 00:21:29,475
Yeah.

230

00:21:29,475 --> 00:21:32,355
Because it's a different thing when you look on the layout.

231

00:21:32,515 --> 00:21:39,155
A lot of people, when you show them the layout, it's hard for them to see what does it really mean once it's built.

232

00:21:39,395 --> 00:21:45,410
But, it helped a lot, to, yeah, to play operator in your process.

233

00:21:45,970 --> 00:21:52,850
And then you figure out, there is a little door missing for the samples or whatever.

234

00:21:53,410 --> 00:21:53,970
Yeah.

235

00:21:53,970 --> 00:21:56,370
So it was very much used.

236

00:21:56,370 --> 00:22:02,945
And so also during the project, digitalization played a big role.

237

00:22:03,345 --> 00:22:11,745
We tested more things than we at the end used because we also had a lot of things which we tried and we figured out.

238

00:22:12,280 --> 00:22:15,400
We are probably a few years too early for that.

239

00:22:15,640 --> 00:22:25,240
For example, we used virtual reality or augmented reality glasses because one idea was,

240
00:22:25,685 --> 00:22:35,205
what if an operator has no monitor and only the glasses on his on his
nose and, runs through the batch record with gesture?

241
00:22:35,765 --> 00:22:36,085
Yeah?

242
00:22:38,070 --> 00:22:39,030
Did not work.

243
00:22:39,030 --> 00:22:40,870
The connection was not sufficient.

244
00:22:40,870 --> 00:22:45,190
And they are simply too heavy to have some eight hours on your nose.

245
00:22:45,190 --> 00:22:45,590
Yeah?

246
00:22:45,590 --> 00:22:47,510
So that is something we tried.

247
00:22:47,590 --> 00:22:52,150
And I can give you at least twenty twenty examples where we tried new
technologies.

248
00:22:52,865 --> 00:22:55,185
And finally we came to the result.

249
00:22:55,265 --> 00:23:00,385
It may work maybe in five years, but today it does not work.

250
00:23:00,705 --> 00:23:01,105
Yeah.

251
00:23:01,105 --> 00:23:08,305
The industry talks a lot about Farmer four point o, but Zelyta
demonstrates it in action.

252
00:23:09,040 --> 00:23:18,640

And what are some of the technologies or combinations of technologies that have been most transformative in creating an autonomous, connected

253

00:23:18,640 --> 00:23:20,160
manufacturing environment?

254

00:23:20,720 --> 00:23:26,135
Well, I would say that, the most transformative element is probably not one technology.

255

00:23:26,135 --> 00:23:28,855
I'd put it like you just said it.

256

00:23:29,415 --> 00:23:38,935
It's probably the effective combination of technologies, devices, and software systems into one connected ecosystem.

257

00:23:40,670 --> 00:23:50,030
Because a fully automized pharmaceutical production facility is only possible if you manage to integrate ERP, MES

258

00:23:50,030 --> 00:23:57,215
systems, production equipment, robotics, and logistics equipment into one ecosystem.

259

00:23:58,175 --> 00:24:07,690
And creating one functional ecosystem really is not that easy, and, it required a couple novel solutions that,

260

00:24:08,010 --> 00:24:13,530
we noticed are not available or were not available, on the market anywhere.

261

00:24:13,530 --> 00:24:20,410
And one example which stands out is the production flow control system, the PFC system.

262

00:24:22,115 --> 00:24:32,115
The PFC system was custom developed by the SOLIDA-1 team, and it serves as the central orchestration layer for

263

00:24:32,595 --> 00:24:34,435
process driven material flow.

264

00:24:35,400 --> 00:24:42,920

What it does is it tracks continuously the real time location of all logistics devices.

265

00:24:43,560 --> 00:24:50,760

It generates transport orders and communicates with the AGV fleet, the automated guided vehicles.

266

00:24:51,475 --> 00:25:01,235

And it thus creates the interface between the material flow on the shop floor in real life and the manufacturing execution ecosystem, the

267

00:25:01,235 --> 00:25:02,915

MES system on the factory level.

268

00:25:04,360 --> 00:25:13,160

And this interface so far typically relied on an operator, you know, that was responsible for oversight,

269

00:25:13,640 --> 00:25:14,840

prioritization.

270

00:25:15,480 --> 00:25:25,395

And what we achieved is that the PFC provides this level of intelligence that previously was provided by an operator and allows us

271

00:25:25,395 --> 00:25:27,395

to reach a new level of automation.

272

00:25:27,395 --> 00:25:36,780

And I think that's what Pharma four point o in practice is, is it's integrating equipment, software, tools, and data into

273

00:25:36,780 --> 00:25:42,220

one connected and, I'm gonna say, increasingly intelligent operating system.

274

00:25:42,700 --> 00:25:51,255

So following along with that, one particular interesting point is that automation isn't replacing people necessarily.

275

00:25:51,495 --> 00:25:52,935
It's changing how they work.

276
00:25:53,655 --> 00:26:03,360
So how have employee roles evolved, within this facility, and what new skills are becoming most important in

277
00:26:03,360 --> 00:26:06,160
such a highly automated facility?

278
00:26:06,560 --> 00:26:13,680
Yeah, as you said, a SOLIDA-1 is highly automated, but it is for sure not a people-free facility.

279
00:26:15,040 --> 00:26:25,005
The role of people moves in general away from repetitive and physical demanding activities, what we have in current, in, let's

280
00:26:25,005 --> 00:26:34,950
say, more older facilities right now, towards, more the role of supervising the process, root cause analysis, and troubleshooting, and

281
00:26:34,950 --> 00:26:36,390
process optimization.

282
00:26:37,030 --> 00:26:46,550
In the first half of career, I was always working in operations and spent a lot of years as a plant manager in different plants.

283
00:26:47,015 --> 00:26:56,775
And usually, I needed 90% of if I had a problem, I needed 90% of the available time to get some data, and then I had a few minutes left

284
00:26:56,775 --> 00:26:59,655
to figure out what do the data mean.

285
00:26:59,815 --> 00:27:00,055
Yeah?

286
00:27:00,590 --> 00:27:06,750
And that, I think, is now completely the other way around, at least.

287

00:27:06,830 --> 00:27:07,390

Yeah?

288

00:27:07,390 --> 00:27:14,910

You get the data, and you can spend your time in what does it mean, where is the really problem, and how to solve it.

289

00:27:14,910 --> 00:27:15,150

Yeah?

290

00:27:15,315 --> 00:27:25,075

And that was, in the past, very exhausting to get data because sometimes you need to sit down and simply, with a piece of paper, write things down from batch, from

291

00:27:25,075 --> 00:27:27,235

batch, from batch, and each batch.

292

00:27:27,235 --> 00:27:27,315

Yeah?

293

00:27:29,040 --> 00:27:35,360

The skill set of people is moving towards a better understanding of the overall process.

294

00:27:35,440 --> 00:27:35,680

Yeah?

295

00:27:35,680 --> 00:27:39,600

You need people who more understand what is the overall process.

296

00:27:39,600 --> 00:27:44,975

Not somebody who's only an expert in a tabletting machine is running a bigger machine.

297

00:27:44,975 --> 00:27:45,375

Yeah?

298

00:27:45,375 --> 00:27:52,255

The understanding of the way of working of machines and systems and the meaning and interpretation of technical data.

299

00:27:52,895 --> 00:28:02,500

And automation and data, of course, make inefficiency and process problems much more transparent in typical manually factories and

300

00:28:02,500 --> 00:28:08,340

develop more push to solve problems instead of developing creative workarounds.

301

00:28:08,340 --> 00:28:08,820

Yeah?

302

00:28:08,980 --> 00:28:18,555

So, I think, to be honest, I think very often people try find a way to work around the problem instead of solving

303

00:28:18,555 --> 00:28:19,035

it.

304

00:28:19,035 --> 00:28:19,515

Yeah?

305

00:28:19,915 --> 00:28:29,250

Automation does not remove expertise from manufacturing, but it allows people more, especially in operation, to

306

00:28:29,250 --> 00:28:38,610

better develop and use the expertise, really do the things that a person should do and not do things which do not create value.

307

00:28:39,535 --> 00:28:49,375

But it also means that during the design and implementation of a facility, you need to be more precise in the process understanding

308

00:28:49,615 --> 00:28:50,655

and planning.

309

00:28:50,975 --> 00:28:51,215

Yeah.

310

00:28:51,215 --> 00:29:00,040

In the past, maybe you you have a room, you put a tablet press in the middle, and you say the operator will figure out how to run it.

311
00:29:00,200 --> 00:29:00,680
Yeah?

312
00:29:00,840 --> 00:29:04,440
But if you automate it, you need to make up your mind.

313
00:29:04,440 --> 00:29:05,960
Where is the pallet coming in?

314
00:29:06,195 --> 00:29:09,075
How to lift it to the machine?

315
00:29:09,075 --> 00:29:09,635
Yeah?

316
00:29:09,635 --> 00:29:11,555
How to get the machine running?

317
00:29:11,555 --> 00:29:13,075
Who starts the recipe?

318
00:29:13,075 --> 00:29:22,830
So you you need basically, I would say, you need you are more forced to do what you should do in other facilities also, more precise and good

319
00:29:22,830 --> 00:29:28,430
planning, and not, puts a problem later on the shoulders of the operator.

320
00:29:30,110 --> 00:29:30,590
Yeah.

321
00:29:30,590 --> 00:29:40,285
So this facility introduces a ballroom manufacturing concept for oral solid dosage production, which allows robots, your automated

322
00:29:40,285 --> 00:29:45,085
guided vehicles, and materials to flow freely throughout the facility.

323
00:29:45,725 --> 00:29:52,130
What advantages has this approach delivered compared to traditional manufacturing layouts?

324

00:29:52,770 --> 00:29:53,170

Yeah.

325

00:29:53,170 --> 00:30:01,090

So traditional layouts plays every process step typically in a separate room, which, creates an interface

326

00:30:02,715 --> 00:30:05,355

interrupting the manufacturing process flow.

327

00:30:05,675 --> 00:30:14,955

And, what we decided is to put nearly all major process units into one open multifunctional space,

328

00:30:15,700 --> 00:30:17,780

which we call the ballroom.

329

00:30:18,340 --> 00:30:27,940

And, this ballroom gives us a completely new level of production flexibility as it enables free movement

330

00:30:28,165 --> 00:30:37,205

of robots and AGVs between these process units that are not interrupted by doors, material locks, or other pieces of equipment.

331

00:30:37,765 --> 00:30:47,750

And what this does is it allows us to change the production process very flexibly and very quickly without requiring any

332

00:30:47,750 --> 00:30:48,950

reconfiguration.

333

00:30:49,670 --> 00:30:55,670

And it also means that, equipment access is much easier for maintenance, for example.

334

00:30:56,235 --> 00:31:05,995

And looking into future requirements, it gives us a a much higher level of adaptability, in terms of replacing or

335

00:31:05,995 --> 00:31:07,115

upgrading equipment.

336

00:31:09,480 --> 00:31:18,360

Zooming out a little bit, what it does on the facility level is that, using the ballroom concept enables a roughly

337

00:31:18,760 --> 00:31:26,485

25% reduction in building footprint because we're eliminating, duplicate logistics and traffic space.

338

00:31:27,365 --> 00:31:34,725

And, what I wanna point out, the the ballroom doesn't limit productivity or efficiency.

339

00:31:35,690 --> 00:31:42,890

Because what we do is, we produce up to five simultaneous batches of the same product within the ballroom.

340

00:31:44,330 --> 00:31:49,930

So it's nothing that would bring our, our efficiency down.

341

00:31:51,665 --> 00:31:53,905

It basically gives us flexibility.

342

00:31:53,905 --> 00:32:03,720

And through using technology, automation tools, we manage to keep the efficiency, at a good level

343

00:32:03,720 --> 00:32:06,440

for for us from a manufacturing standpoint.

344

00:32:06,440 --> 00:32:12,760

So you've described SLETA-one as a major step towards lights out manufacturing.

345

00:32:12,920 --> 00:32:21,945

How close is the industry to truly autonomous pharmaceutical production, and what key capabilities still need to mature?

346

00:32:22,905 --> 00:32:29,305

I would say ZOLIDA1 demonstrates that a high level of automation is already possible in pharmaceutical production.

347

00:32:29,650 --> 00:32:37,970

And if you look in other industries, like car industry, SOLIDA-1 is maybe even more than normal than the exception,

348

00:32:39,330 --> 00:32:39,890

yeah?

349

00:32:41,170 --> 00:32:49,775

Major activities like material handling, weighing, the different formulation production steps, mostly cleaning, not completely.

350

00:32:50,095 --> 00:32:54,415

Documentation are automated and digitally connected.

351

00:32:54,895 --> 00:33:04,230

However, the next step from my perspective would be to use the data and artificial intelligence to let the factory optimize

352

00:33:04,230 --> 00:33:05,110

itself.

353

00:33:05,750 --> 00:33:06,310

Yeah?

354

00:33:06,870 --> 00:33:10,950

And we had this in mind from the beginning on when we started.

355

00:33:10,950 --> 00:33:14,045

Artificial intelligence was freak stuff.

356

00:33:14,045 --> 00:33:17,645

We heard about it, but we were not sure what comes out later on.

357

00:33:17,725 --> 00:33:18,285

Yeah?

358

00:33:19,885 --> 00:33:29,360

But so I could now say it was all planned, but I would in reality, there's more good luck that we builded a

359

00:33:29,360 --> 00:33:33,840

facility with this data backbone, which you need to use AI.

360

00:33:33,920 --> 00:33:34,480

Yeah?

361

00:33:35,120 --> 00:33:45,115

By luck, we we did it exactly in the right moment because AI just in the last two years came to birth really and is now more and more

362

00:33:45,115 --> 00:33:45,915

used.

363

00:33:46,955 --> 00:33:56,510

I would say if he goes this way that you say one day, yeah, it it does take care of himself, The biggest hurdle probably

364

00:33:56,670 --> 00:34:04,910

is in the heads of the people to accept that process parameters may be changed one day without the approval of a person.

365

00:34:05,230 --> 00:34:15,185

And to be honest, we already could do this, but I think that is something which the

366

00:34:15,265 --> 00:34:16,705

same like with the ballroom.

367

00:34:16,705 --> 00:34:21,905

We we asked authorities to come in before we and showed them the concept.

368

00:34:21,905 --> 00:34:24,330

Because the question is, you can have a great idea.

369

00:34:24,330 --> 00:34:27,370

If it does not get accepted, you have a problem.

370

00:34:27,450 --> 00:34:27,930

Yeah?

371

00:34:27,930 --> 00:34:37,595

And I I think also that is something where we need to maybe to give the people some time to accept it, that process parameters

372

00:34:37,595 --> 00:34:42,795

get optimized by artificial intelligence.

373

00:34:43,915 --> 00:34:53,610

Furthermore, what I think is a deeper understanding of the physical properties of the materials will make operation more predictive and foster automation.

374

00:34:53,770 --> 00:34:57,690

I think their pharmaceutical industry has some way to go.

375

00:34:58,170 --> 00:35:08,125

And finally, it will be very important when you go for automated production to develop processes with the later automation already in mind.

376

00:35:08,445 --> 00:35:18,270

For example, you should avoid manually sampling and IPCs and use much more automated online analytics Because it

377

00:35:18,270 --> 00:35:19,310

does not make sense.

378

00:35:19,310 --> 00:35:28,990

You you save the operator, runs the machine, but then somebody comes with a sample glass and takes a sample, goes back to the IPC lab, and then the machine needs to wait for the result.

379

00:35:29,310 --> 00:35:39,115

You know, I spoke with an executive in the data center AI, industry, and, he said that, really, you know, AI is

380

00:35:39,115 --> 00:35:47,870

based on sophisticated statistics, which is what pharmaceutical manufacturing, process control,

381

00:35:49,070 --> 00:35:58,910

identifying the process parameters is really based on, and that we should be using, the the AI

382

00:35:59,445 --> 00:36:06,005

for more statistical applications and less so for the sort of ChatGPT kind of stuff.

383

00:36:06,725 --> 00:36:16,070

But looking looking ahead, AI enabled decision making, digital twins, predictive maintenance,

384

00:36:16,630 --> 00:36:21,270

and real time quality monitoring have been noted as the next phase of Pharma four point o.

385

00:36:22,310 --> 00:36:26,870

Which of these innovations do you believe will have the greatest impact over the next five years?

386

00:36:27,695 --> 00:36:37,535

So I'd say that the the the real transformation will probably come from a combination of of these technologies, and a

387

00:36:37,535 --> 00:36:45,470

combination of these technologies around, trusted, contextualized, and basically high quality manufacturing and process data.

388

00:36:47,710 --> 00:36:55,310

Because in order to leverage the potential of data, I would honestly even put these technologies in somewhat of an order.

389

00:36:55,935 --> 00:36:56,335

Right?

390

00:36:56,335 --> 00:37:03,615

I mean, real time monitoring enables a new level of transparency of the state of the manufacturing process.

391

00:37:04,655 --> 00:37:12,160

This transparency, again, enables the application of, for example, digital twins to simulate what might happen.

392

00:37:12,720 --> 00:37:20,400

And, again, as the next step, AI helps to identify patterns with the goal to create predictive tools.

393

00:37:21,485 --> 00:37:28,765

And I'd say, therefore, these technologies kind of mesh and work together to, create real life value.

394

00:37:29,405 --> 00:37:39,210

And what we did at SOLIDA-1, we made sure to get the foundation for all of this right, meaning we're collecting,

395

00:37:39,370 --> 00:37:48,810

I'm gonna say, near real time data holistically throughout the entire manufacturing process, and we're merging it into one integrated database.

396

00:37:49,755 --> 00:37:59,115

And this allows us to continuously integrate, further develop, and combine technologies to drive the progression that we currently see

397

00:37:59,115 --> 00:38:09,040

from, I would say, connected operations towards intelligent, predictive, and still well governed manufacturing.

398

00:38:10,000 --> 00:38:19,200

And maybe allow me to allow me to say one thing, regarding the, you know, ChatGPT, chatbot, comment you made earlier, and I completely agree with you.

399

00:38:19,625 --> 00:38:24,265

The statistical analysis is probably where the real value lies.

400

00:38:24,665 --> 00:38:34,460

But we see one example at SOLIDA-1 that goes a little bit in the direction of the chatbot functionality, which is that now that we

401

00:38:34,460 --> 00:38:44,395

collect all the data, we can give operators the, application and the chance to use GenAI tools to kind

402

00:38:44,395 --> 00:38:53,435

of search in the data and make it easier to access the information that they need, which doesn't replace the analytics and, you know, it doesn't help all the way.

403

00:38:53,915 --> 00:38:58,715

But I'm sure you've done it before if you try to find information in a large document.

404

00:38:58,715 --> 00:39:02,920

It's it's a lot easier to just ask ChatGPT, give me a little update.

405

00:39:02,920 --> 00:39:05,000

That's what we do at SOLIDA-1 as well.

406

00:39:06,200 --> 00:39:16,115

Helping the operators, you know, look in batch records, try to find information on on deviations, equipment status, and, you know, help them

407

00:39:16,115 --> 00:39:18,115

get the information as fast as possible.

408

00:39:18,435 --> 00:39:20,035

Great, great.

409

00:39:20,195 --> 00:39:29,570

So for organizations considering their own digital transformation journey, what are the biggest lessons learned from this project that they can apply to

410

00:39:29,570 --> 00:39:35,810

today regardless of the size or maturity of their manufacturing operations?

411

00:39:36,450 --> 00:39:37,010

Yeah.

412

00:39:37,650 --> 00:39:47,185

Let's start with a simple truth - Pharma four point o or digitalization or however you call it is, not just a technology.

413

00:39:47,745 --> 00:39:52,385

It is an operational transformation that changes the way how we work.

414

00:39:52,740 --> 00:40:02,740

Because things it's it's not just an aids that you, instead of typing yourself or writing on a piece of paper, suddenly you have

415

00:40:02,740 --> 00:40:06,515

a computer and you print something, but basically do the same.

416

00:40:06,675 --> 00:40:07,875

Here it is different.

417

00:40:07,955 --> 00:40:10,035

It changes the way how you work.

418

00:40:10,835 --> 00:40:12,595

You need to better understand.

419

00:40:12,595 --> 00:40:22,420

In order to do so, you need to better understand your operational processes in detail and the purpose of them not hesitating to change them

420

00:40:22,420 --> 00:40:23,460

for the better.

421

00:40:23,940 --> 00:40:29,780

That is not only valid for the project team, but as well for the operations team later on.

422

00:40:30,660 --> 00:40:40,505

Second, any new facility, new production line or even piece of equipment if you have smaller changes because you do not everybody builds a

423

00:40:40,505 --> 00:40:42,985

new facility every second day.

424

00:40:43,625 --> 00:40:47,865

All of that is the opportunity to change the way of working.

425

00:40:48,400 --> 00:40:52,480

I would say never just copy old stuff.

426

00:40:52,640 --> 00:40:57,120

Take the opportunity to think about if you may change something.

427

00:40:57,680 --> 00:41:02,720

Third, in any project, start your digitalization subproject on day one.

428

00:41:03,545 --> 00:41:09,705

In the the history, very often the focus on investment project was on steel and concrete.

429

00:41:10,105 --> 00:41:19,950

The digital factory is at least as important as the steel and concrete factory, even if you don't see

430

00:41:19,950 --> 00:41:22,670

that much and if the CapEx is not so high.

431

00:41:22,910 --> 00:41:27,630

But in order that it works, it is very important.

432

00:41:28,110 --> 00:41:33,345

We identified and involved the execution companies, for example, already.

433

00:41:34,225 --> 00:41:34,785

Yeah.

434

00:41:34,945 --> 00:41:41,825

Fourth point, if you have a complex project, involves the partner companies in an early phase, as I already said.

435

00:41:41,825 --> 00:41:41,985

Yeah?

436

00:41:42,400 --> 00:41:48,000

But not only them, also the users, the QA, etcetera, early on.

437

00:41:48,000 --> 00:41:49,040

Very important.

438

00:41:49,600 --> 00:41:58,585

For example, we identified and involved the execution companies already in the very early phase of the project starting FEO two.

439

00:41:58,585 --> 00:42:04,025

Was additional work because you do something usually you do for the bidding process.

440

00:42:04,025 --> 00:42:08,185

We did this in early phase, but it paid off a lot.

441

00:42:09,225 --> 00:42:17,400

Topic number five, develop design principles, standards, and stick to them without being not flexible to improve them.

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00:42:17,480 --> 00:42:22,760

That reduces workload and helps you to focus on the really complicated stuff.

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00:42:23,415 --> 00:42:29,095

Because in the digital factory, like I said, you need to be more precise in planning.

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00:42:29,095 --> 00:42:31,255

You need to be more professional.

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00:42:31,575 --> 00:42:41,140

So try to get the easy stuff away, work with standards so you focus with your people on the really important things.

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00:42:41,700 --> 00:42:47,620

The majority of the money you spend on is on brain and not on the square meter cost of concrete.

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00:42:48,260 --> 00:42:56,055

So avoid tight custom made designs, which create a lot of complexity later on in the engineering.

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00:42:56,535 --> 00:43:01,095

Six, and that comes to a word we used already, modularity.

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00:43:01,095 --> 00:43:04,695

Use modularity and clear interfaces between the modules.

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00:43:05,320 --> 00:43:11,800

And that's not because, for the sake of modularity, that helps you to reduce complexity.

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00:43:11,800 --> 00:43:17,160

You have clear interfaces, and each Lego block has a role and plays its role.

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00:43:17,320 --> 00:43:22,635

And if something changes, this block changes, but, yeah, your whole building changes.

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00:43:22,715 --> 00:43:24,635

It makes the thing much easier.

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00:43:24,955 --> 00:43:31,595

And that does not only work for building architecture, but that is something where I can see it easily with the modules and so on.

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00:43:31,930 --> 00:43:41,690

That also works for equipment setup and IT systems, yeah, in which, for example, we try to separate

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00:43:41,690 --> 00:43:50,465

the data from the software because your software may change in the next years, but you want to keep your data.

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00:43:50,545 --> 00:43:51,025

Yeah?

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00:43:51,025 --> 00:43:57,905

So a factory today is more like an iPhone, where you can change the software.

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00:43:58,465 --> 00:44:07,060

And even if in five years your program to show your photos is different, you still have your data for the photos.

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00:44:07,300 --> 00:44:07,860

Yeah?

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00:44:08,020 --> 00:44:17,815

And that is something flexibility in the design helps you a lot when you keep things separated, for example, not mixing

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00:44:17,815 --> 00:44:19,095

data with software.

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00:44:19,255 --> 00:44:22,135

Well, this has been a great conversation.

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00:44:23,735 --> 00:44:26,375

This project is really cutting edge.

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00:44:26,900 --> 00:44:36,100

The innovation of the overall process design, the open ballroom, the use of integrated, digital,

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00:44:36,580 --> 00:44:46,355

technologies, how you're changing how people, what their roles are, and basically upskilling, what they

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00:44:46,355 --> 00:44:47,315

focus on.

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00:44:47,875 --> 00:44:49,875

This is all super fantastic.

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00:44:49,875 --> 00:44:54,355

And so I'd like to thank Juergen and Christophe for their time with us today.

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00:44:55,075 --> 00:44:59,940

It is great to hear more about Bayer's SOLIDA-1 facility.

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00:45:00,900 --> 00:45:07,620

That brings us to the end of another episode of the ISPE podcast, shaping the future of pharma.

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00:45:08,580 --> 00:45:17,415

Please be sure to subscribe so that you don't miss future conversations with the innovators, experts, and changemakers driving our industry forward.

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00:45:18,535 --> 00:45:28,270

On behalf of all of us at ISPE, thank you for listening, and we'll see you next time as we continue to explore the ideas, trends, and

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00:45:28,270 --> 00:45:30,910

people shaping the future of pharma.