



Creating partnership through improved communication

Technology transfer of an innovative drug delivery system: The “Accordion Pill”

PDA Israel

*Technology Transfer and Working with CMO/CDMO
Tel Aviv, 4th March 2019*

*Ronny Reinberg
Intec Pharma*

- Intec Pharma introduction
- The Accordion Pill Technology
- CMO selection
- LTS introduction
- Project management approaches

Forward Looking Statements

This presentation by Intec Pharma Ltd. (referred to as “we” or “our”) contains forward-looking statements about our expectations, beliefs and intentions regarding, among other things, our product development efforts, business, financial condition, results of operations, strategies, plans and prospects. In addition, from time to time, we or our representatives have made or may make forward-looking statements, orally or in writing. Forward-looking statements can be identified by the use of forward-looking words such as “believe”, “expect”, “intend”, “plan”, “may”, “should”, “could”, “might”, “seek”, “target”, “will”, “project”, “forecast”, “continue” or “anticipate” or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including those described in the sections entitled “risk factors” in the documents that we file with the Securities and Exchange Commission.

We believe these forward-looking statements are reasonable; however, these statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. Given these uncertainties, you should not rely upon forward-looking statements as predictions of future events.

All forward-looking statements attributable to us or persons acting on our behalf speak only as of the date of this presentation and are expressly qualified in their entirety by the cautionary statements included in this presentation. We undertake no obligations to update or revise forward-looking statements to reflect events or circumstances that arise after the date made or to reflect the occurrence of unanticipated events, except as required by applicable law. In evaluating forward-looking statements, you should consider these risks and uncertainties.

The presentation contains information about investigation-stage drug products under development, which have not yet been approved by the FDA for commercial distribution in the United States. All representations in this Presentation are based upon investigations in certain clinical and other research, but which accordingly should not be construed as general claims for the safety or efficacy of the products when used by patients.

Intec Pharma



The Accordion Pill™ (AP)

Proprietary oral delivery system of drugs on film



Parkinson's Program Phase 3

Unencumbered WW rights



Utilizing 505(b)(2) regulatory pathway

Faster and less expensive
pathway to market

AP Cannabinoids (CBD, THC)

Various indications in Phase 1



NOVARTIS

Proprietary drug evaluation



Future potential value drivers

Potential for multiple
collaborations



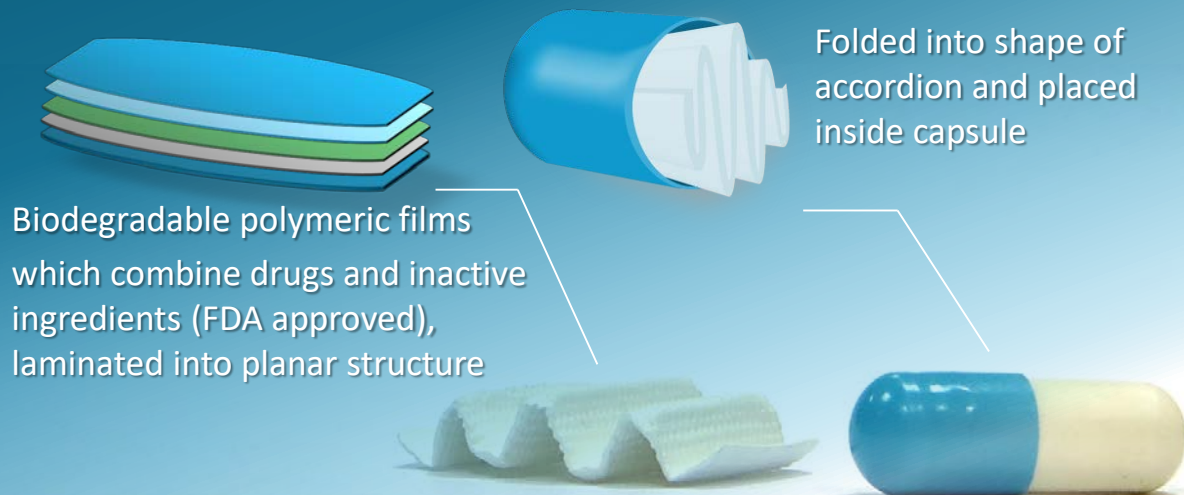
INTEC PHARMA

What we are about: The Accordion Pill (AP)

AP Platform Technology

A customized solution for each application

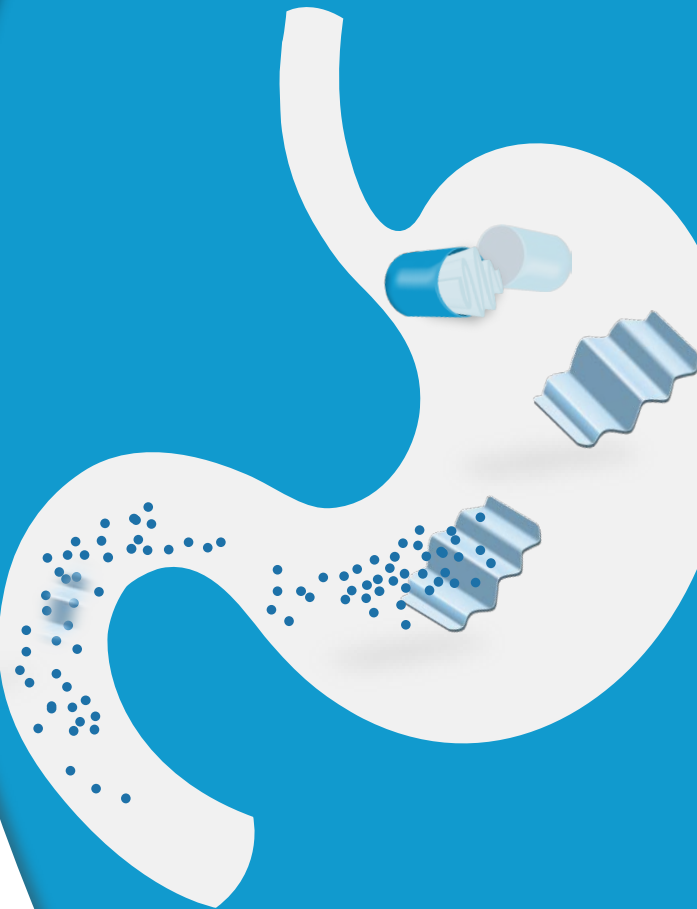
- *Each film layer can be designed as a different delivery system*
- *Mix and match multiple layers, multiple drugs*



Accordion Pill™ Unique Advantages:

- *Enhanced gastric retention*
- *Improved PK*
- *High drug loading*
- *Fix dose combination*
- *Multiple drug release profiles*
- *Tested in Multiple clinical trials (PK and efficacy studies)*

The Accordion Pill: A new platform for oral drug delivery



AP capsule dissolves and outer layers facilitate unfolding mechanism of films

Layers comprise an inner, controlled release drug-containing layer, and/or immediate release layer(s) for multiple drug release profiles and/or fixed-dose combinations

Retained in stomach for up to 12 hours, AP releases drug in controlled manner towards upper part of gastrointestinal tract, where it is absorbed

Once AP is out of stomach, it is fully degraded in small intestine.

AP Movie



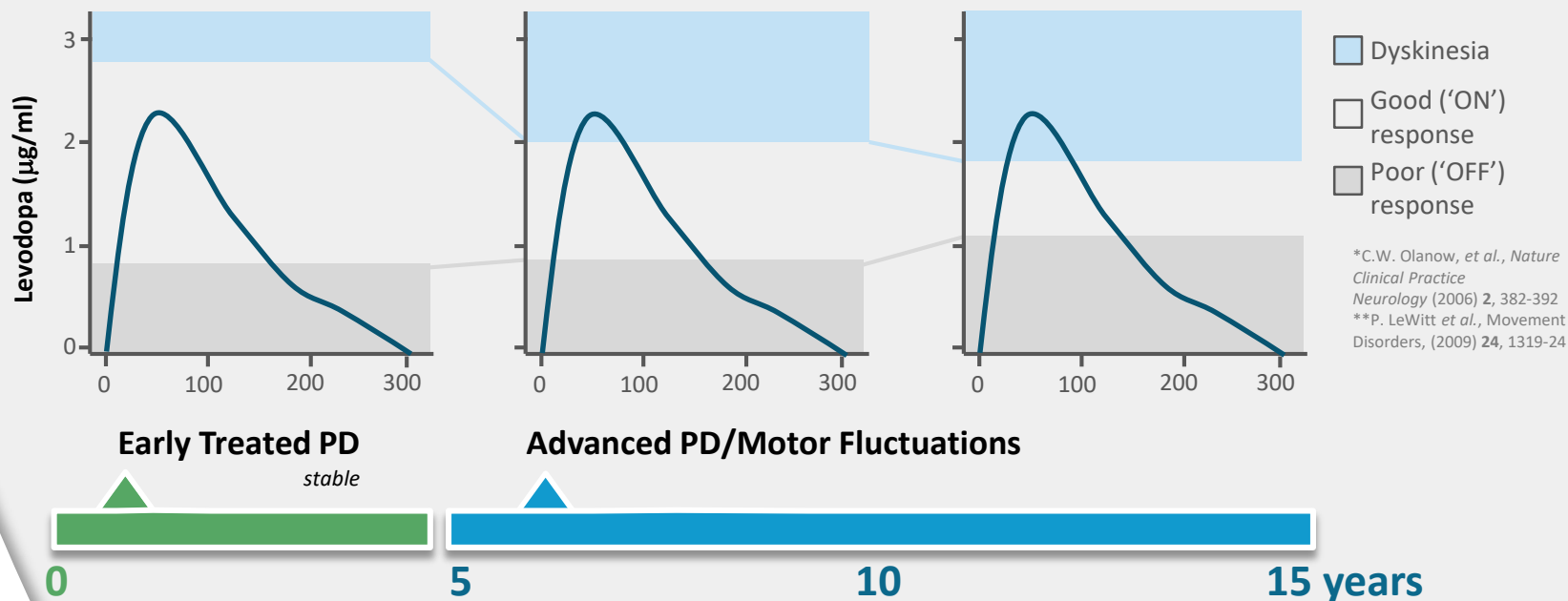
Levodopa PK Is Important In Parkinson's

Majority of PD patients on levodopa therapy

Challenge in improving LD PK

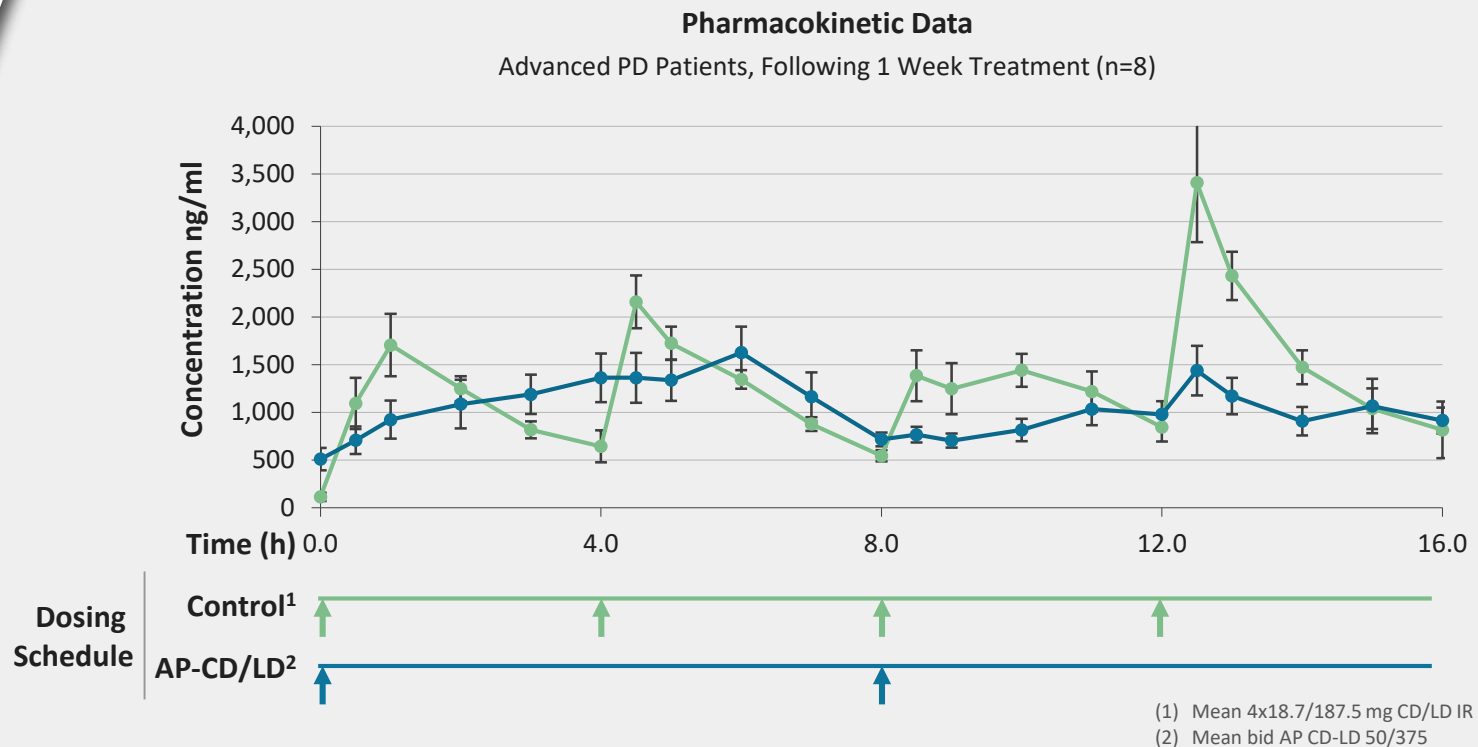
- Levodopa absorption is confined to upper part of GI tract
- Very short half life ~90 min
- Efficacy and AE profile relates directly to plasma levels

Stabilizing LD plasma levels becomes a major factor for improving anti-parkinsonian control in Advanced PD



Phase II AP-CD/LD Results

AP-CD/LD Enables Steady Therapeutic Levodopa Levels



Significantly More Stable PK Achieved by AP-CD/LD

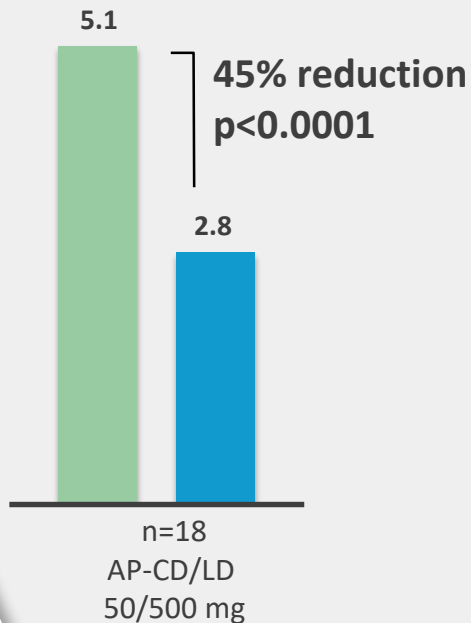
- *Prolonged absorption*
- *Decreased peak to trough ratio*
- *Significantly higher morning plasma levels*

Phase II AP-CD/LD Results

Significant reduction in daily off time and dyskinesia

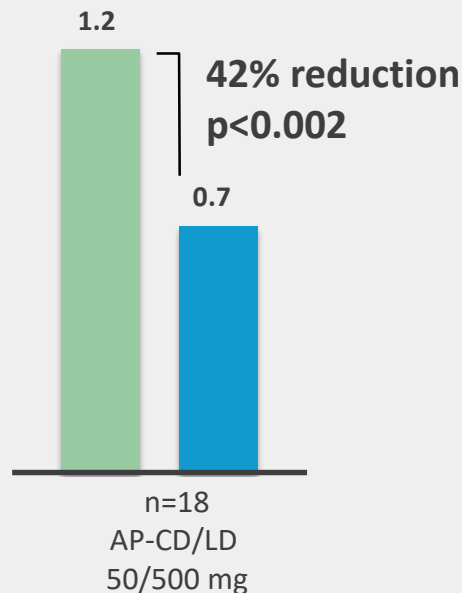
Significantly Reduced Off Time

Off Time (Hours)
Following 3 Weeks Treatment



Significantly Reduced TSD

ON with Troublesome Dyskinesia Time (Hours)
Following 3 Weeks Treatment



Demographics

- Mean Age: 67.7
- Gender: 83% male
- Years LD Therapy: 9.5 +/- 6.7
- Mean LD Dose: 681

Design

- 2 period, 21 day crossover, random order
- Open label dosing
- 4 day off-time assessment after 17-day stabilization
- AP dosed BID vs. 5.3 dose LD in control

Manufacturing

- *Certified GMP facility in Jerusalem, Israel*
- *Automated manufacturing lines*
- *Manufacturing capabilities for all clinical stages, phase 1 to 3*



So...why work with a CMO?

Startup



- ✓ *Innovation*
- ✓ *R&D orientation*
- ✓ *Know how*
- ✓ *Flexibility*
- ✓ *IP*

CMO



- ✓ *Available Infrastructure*
- ✓ *Manufacturing Expertise*
- ✓ *Inspected by regulatory authorities*

- ✓ *Large Vs. Small CMO*
- ✓ *Target markets*
- ✓ *Geography*

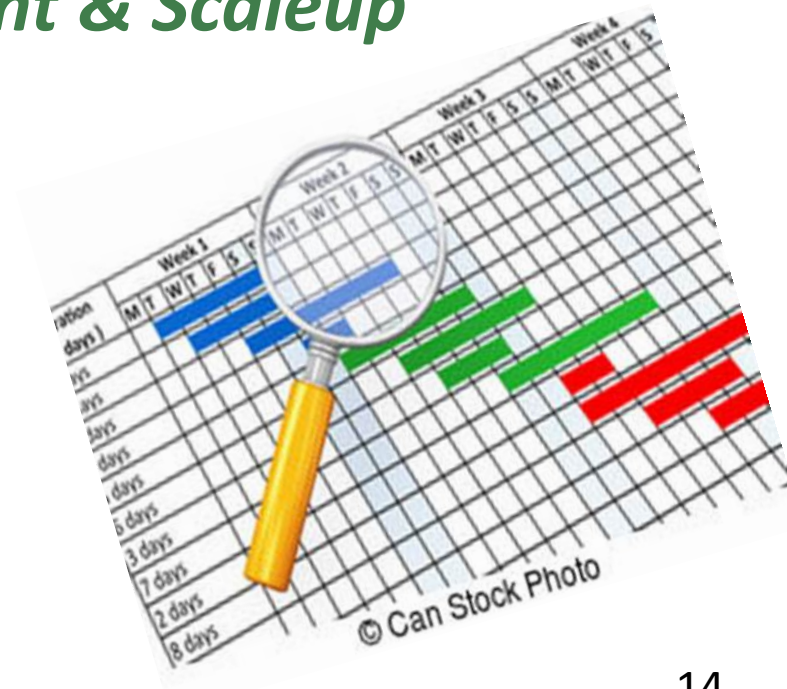
- ✓ *Experts in the specific manufacturing technology*

- ✓ *Leading CMO for innovative drug delivery systems, such as Transdermal Patches (“TTS”) and Oral Thin Films (“OTF”).*
- ✓ *More than 20 marketed products.*
- ✓ *Audited by the FDA, EMA, KFDA, CFDA ,ANVISA etc.*

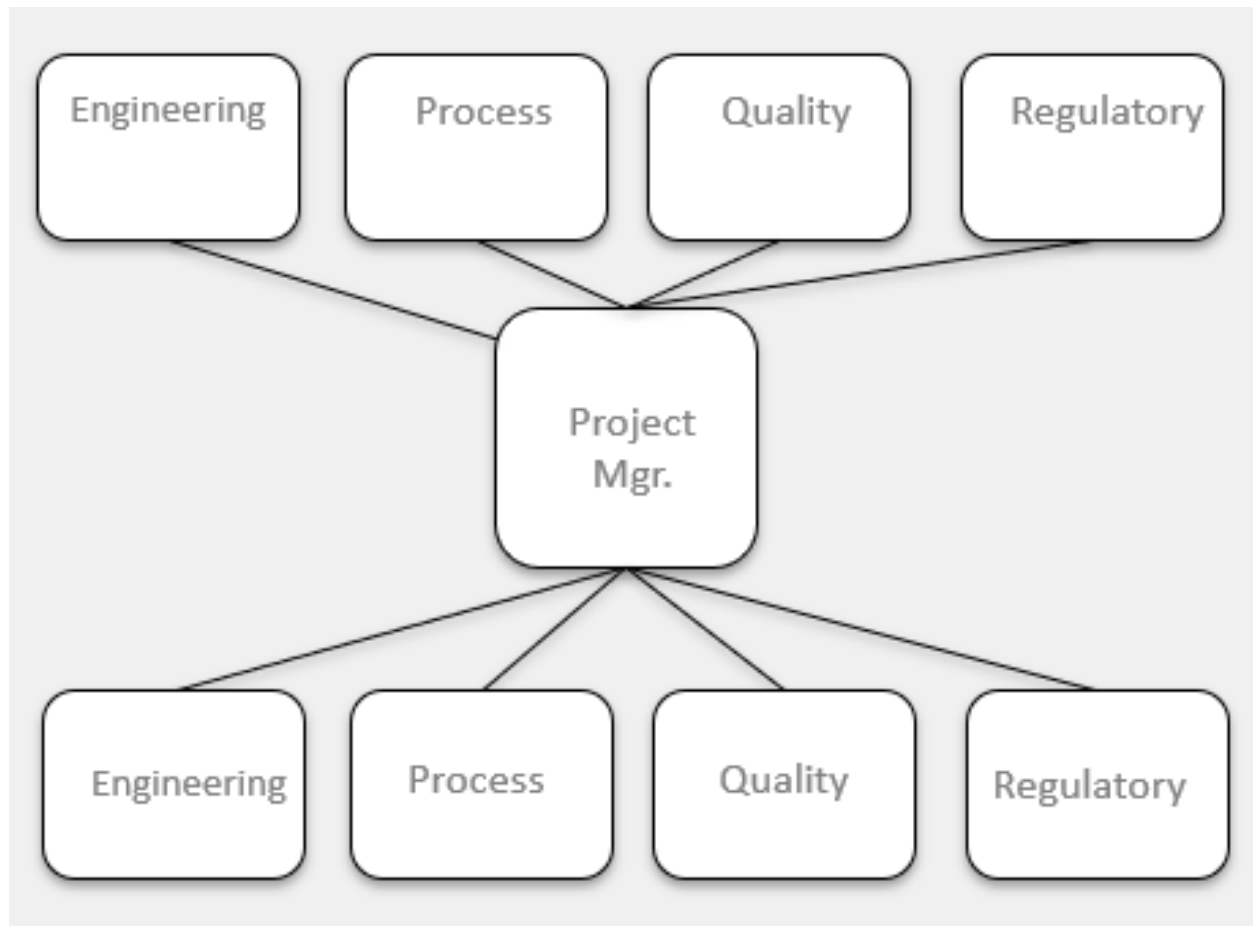


Major Project milestones

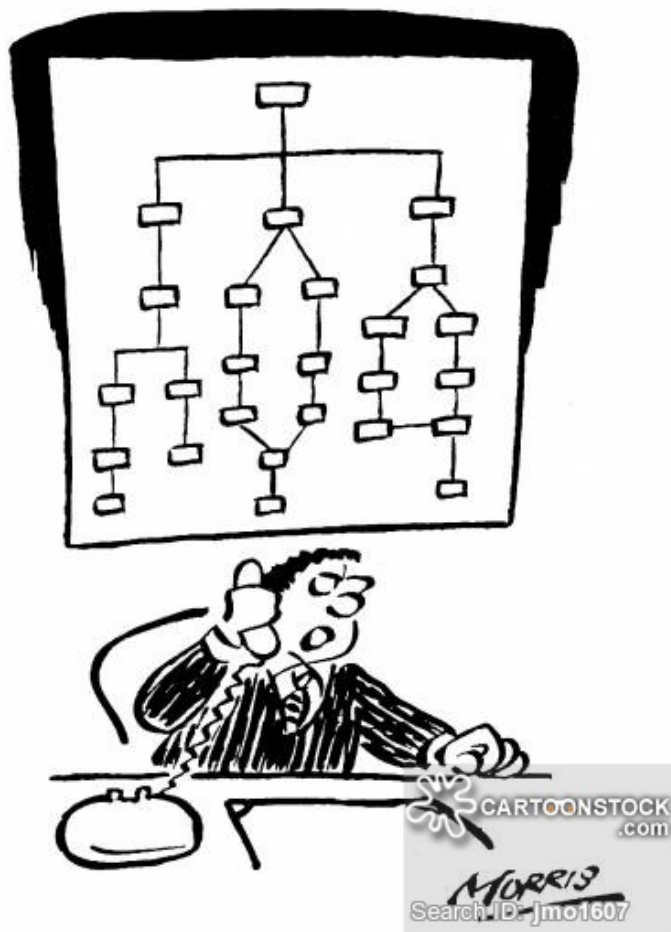
- ✓ *Machines procurement*
- ✓ *Analytical Technology transfer*
- ✓ *Process development & Scaleup*
- ✓ *Process Validation*
- ✓ *NDA Submission*



Classical Project Management

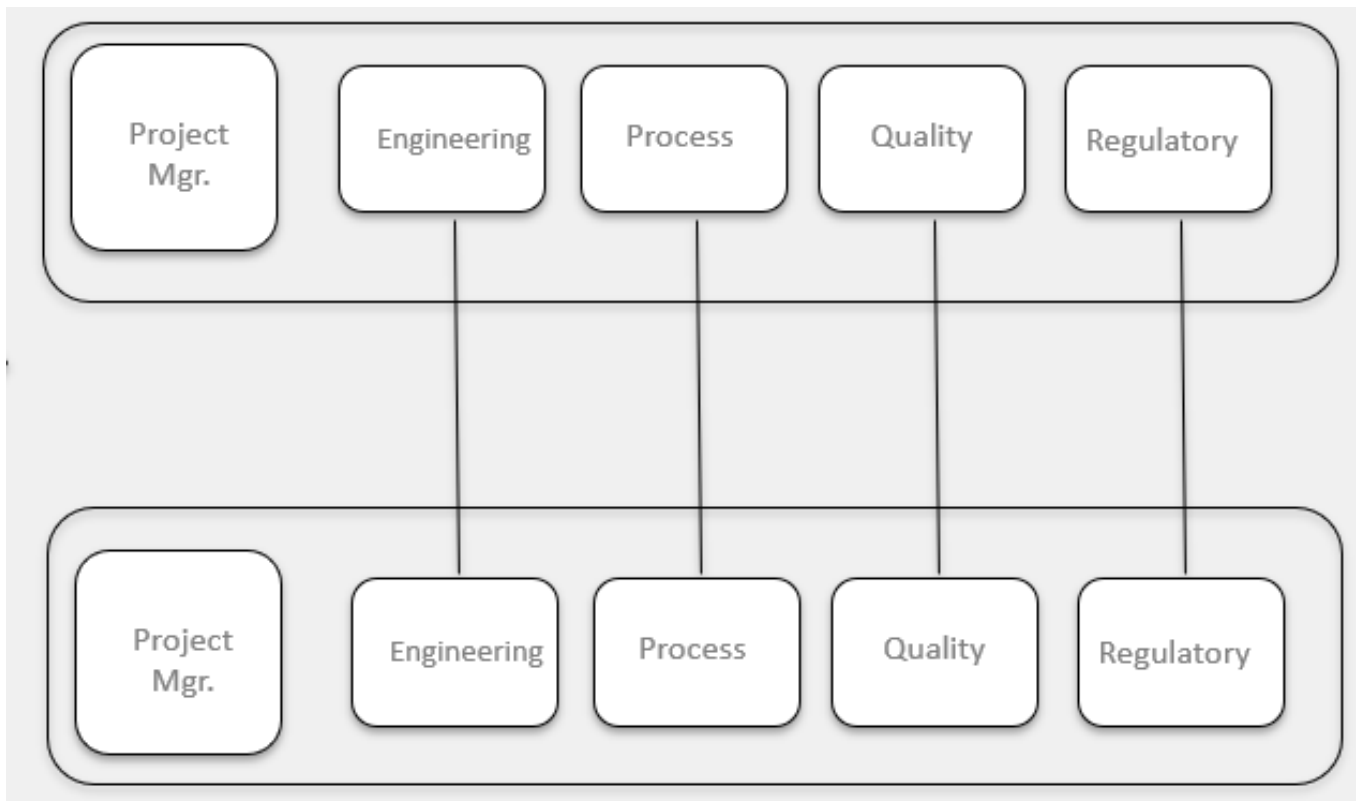


Communication Flow



"Miss Duxbury, put me through
to someone."

Direct Project Management Approach





Thank you!